



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2003

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

\_\_\_\_\_  
(Exact name of registrant as specified in its charter)

New York

13-3444607

\_\_\_\_\_  
(State or other jurisdiction of incorporation or organization)

\_\_\_\_\_  
(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road  
Tarrytown, New York

10591-6707

\_\_\_\_\_  
(Address of principal executive offices)

\_\_\_\_\_  
(Zip Code)

(914) 347-7000

\_\_\_\_\_  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of October 31, 2003:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
<u>Class A Stock, \$0.001 par value</u>	<u>2,390,873</u>
<u>Common Stock, \$0.001 par value</u>	<u>52,910,539</u>

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	September 30, 2003	December 31, 2002
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 298,617	\$ 80,077
Marketable securities	69,723	173,282
Restricted marketable securities	16,333	10,912
Accounts receivable	9,197	4,017
Prepaid expenses and other current assets	2,810	1,829
Inventory	7,698	6,831
Total current assets	404,378	276,948
Marketable securities	6,450	20,402
Restricted marketable securities		10,573
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	83,715	76,825
Other assets	5,958	6,826
Total assets	\$ 500,501	\$ 391,574
<b>LIABILITIES and STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 20,967	\$ 30,309
Deferred revenue, current portion	24,473	9,659
Loan payable	9,296	
Capital lease obligations		150
Total current liabilities	54,736	40,118
Deferred revenue	89,563	5,475
Notes payable	200,000	200,000
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized; 2,390,873 shares issued and outstanding in 2003 2,491,181 shares issued and outstanding in 2002	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized; 52,896,238 shares issued and outstanding in 2003 41,746,133 shares issued and outstanding in 2002	53	42
Additional paid-in capital	670,120	573,184
Unearned compensation	(1,873)	(3,643)
Accumulated deficit	(512,156)	(424,075)
Accumulated other comprehensive income	56	471
Total stockholders' equity	156,202	145,981
Total liabilities and stockholders' equity	\$ 500,501	\$ 391,574

The accompanying notes are an integral part of the financial statements.

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**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS (Unaudited)**  
*(In thousands, except per share data)*

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
<b>Revenues</b>				
Contract research and development	\$ 10,882	\$ 2,780	\$ 28,245	\$ 8,215
Contract manufacturing	6,510	3,786	7,980	8,861
	<u>17,392</u>	<u>6,566</u>	<u>36,225</u>	<u>17,076</u>
<b>Expenses</b>				
Research and development	34,650	34,295	102,757	90,473
Contract manufacturing	4,844	1,637	5,769	4,757
General and administrative	3,601	2,811	10,548	9,167
	<u>43,095</u>	<u>38,743</u>	<u>119,074</u>	<u>104,397</u>
Loss from operations	<u>(25,703)</u>	<u>(32,177)</u>	<u>(82,849)</u>	<u>(87,321)</u>
<b>Other income (expense)</b>				
Investment income	1,285	2,378	3,594	7,703
Interest expense	(2,982)	(3,017)	(8,826)	(9,066)
	<u>(1,697)</u>	<u>(639)</u>	<u>(5,232)</u>	<u>(1,363)</u>
Net loss	<u>(\$27,400)</u>	<u>(\$32,816)</u>	<u>(\$88,081)</u>	<u>(\$88,684)</u>
Net loss per share amounts, basic and diluted	<u>(\$0.52)</u>	<u>(\$0.75)</u>	<u>(\$1.80)</u>	<u>(\$2.02)</u>

**The accompanying notes are an integral part of the financial statements.**

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**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)**  
**For the nine months ended September 30, 2003**  
*(In thousands)*

	Class A Stock		Common Stock		Additional Paid-in Capital	Unearned Compensation
	Shares	Amount	Shares	Amount		
Balance, December 31, 2002	2,491	\$ 2	41,746	\$ 42	\$573,184	(\$3,643)
Issuance of Common Stock in connection with exercise of stock options			575		1,779	
Issuance of Common Stock to Novartis Pharma AG			7,527	8	47,992	
Issuance of Common Stock to Aventis Pharmaceuticals Inc.			2,800	3	44,997	
Issuance of Common Stock to Merck & Co., Inc.			109		1,500	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(4)		(79)	79
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			43		747	
Conversion of Class A Stock to Common Stock	(100)		100			
Amortization of unearned compensation						1,691
Net loss						
Change in net unrealized gain on marketable securities						
Balance, September 30, 2003	2,391	\$ 2	52,896	\$ 53	\$670,120	(\$1,873)

[Additional columns below]

[Continued from above table, first column(s) repeated]

	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Loss
Balance, December 31, 2002	(\$424,075)	\$ 471	\$ 145,981	
Issuance of Common Stock in connection with exercise of stock options			1,779	
Issuance of Common Stock to Novartis Pharma AG			48,000	
Issuance of Common Stock to Aventis Pharmaceuticals Inc.			45,000	
Issuance of Common Stock to Merck & Co., Inc.			1,500	
Forfeitures of restricted Common Stock under Long-Term Incentive Plan				
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			747	
Conversion of Class A Stock to Common Stock				
Amortization of unearned compensation			1,691	
Net loss	(88,081)		(88,081)	(\$88,081)
Change in net unrealized gain on marketable securities		(415)	(415)	(415)
Balance, September 30, 2003	(\$512,156)	\$ 56	\$ 156,202	(\$88,496)

**The accompanying notes are an integral part of the financial statements.**

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**REGENERON PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENT OF CASH FLOWS (Unaudited)**  
*(In thousands)*

	Nine months ended September 30,	
	2003	2002
Cash flows from operating activities		
Net loss	(\$88,081)	(\$88,684)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	8,623	6,405
Non-cash compensation expense	1,954	1,335
Non-cash expense related to a license agreement	1,216	
Changes in assets and liabilities		
Increase in accounts receivable	(5,180)	(1,546)
Decrease (increase) in prepaid expenses and other assets	617	(1,579)
Increase in inventory	(22)	(1,335)
Increase (decrease) in deferred revenue	98,902	(445)
Increase in accounts payable, accrued expenses, and other liabilities	4,267	6,352
Total adjustments	110,377	9,187
Net cash provided by (used in) operating activities	22,296	(79,497)
Cash flows from investing activities		
Purchases of marketable securities	(85,416)	(199,217)
Purchases of restricted marketable securities	(11,024)	(5,500)
Sales or maturities of marketable securities	200,936	119,465
Maturities of restricted marketable securities	16,523	11,000
Capital expenditures	(28,371)	(19,199)
Net cash provided by (used in) investing activities	92,648	(93,451)
Cash flows from financing activities		
Net proceeds from the issuance of stock	94,516	1,468
Borrowings under loan payable	9,230	
Capital lease payments	(150)	(339)
Net cash provided by financing activities	103,596	1,129
Net increase (decrease) in cash and cash equivalents	218,540	(171,819)
Cash and cash equivalents at beginning of period	80,077	247,393
Cash and cash equivalents at end of period	\$ 298,617	\$ 75,574

**The accompanying notes are an integral part of the financial statements.**

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements**

*(Unless otherwise noted, dollars in thousands, except per share data)*

**1. Interim Financial Statements**

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”) have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company’s financial position, results of operations, and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company’s financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2002 Condensed Balance Sheet data was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2002.

Certain reclassifications have been made to the financial statements for the three and nine months ended September 30, 2002 to conform with the current period’s presentation.

**2. Change in Accounting Method**

The Company recognizes revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (“SAB 101”). During the third quarter of 2003, the Company elected to change the method it uses to recognize revenue under SAB 101 related to non-refundable collaborator payments, including up-front licensing payments, payments for development activities, and research progress (milestone) payments, to the Substantive Milestone Method, adopted retroactively to January 1, 2003. Under this method, the Company recognizes revenue from non-refundable up-front license payments, not tied to achieving a specific performance milestone, ratably over the period over which the Company is obligated to perform services. Payments for development activities are recognized as revenue as earned, ratably over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, provided there is no future service obligation associated with that milestone. Previously, the Company had recognized revenue from non-refundable collaborator payments based on the percentage of costs incurred to date, estimated costs to complete, and total expected contract revenue. However, the revenue recognized was limited to the amount of non-refundable payments received. The change in accounting method was made because the Company believes that it better reflects the substance of the Company’s collaborative agreements and is more consistent with current practices in the biotechnology industry. The impact of the adoption of this new revenue recognition

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements**

*(Unless otherwise noted, dollars in thousands, except per share data)*

method was to increase the Company's revenue and reduce the Company's net loss by \$1,531, or \$0.03 per share, in the third quarter of 2003, and to decrease the Company's revenue and increase the Company's net loss by \$304, or \$0.01 per share, for the nine months ended September 30, 2003. There is no impact on the Company's financial results for any period prior to January 1, 2003.

The Company's operating results for the first two quarters of 2003 have been restated in accordance with the new revenue recognition method, and are summarized as follows.

	First quarter ended March 31, 2003 (Unaudited)		Second quarter ended June 30, 2003 (Unaudited)	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Revenues	\$ 10,136	\$ 9,925	\$ 10,532	\$ 8,908
Net loss	(30,110)	(30,321)	(28,736)	(30,360)
Net loss per share, basic and diluted	(\$0.68)	(\$0.68)	(\$0.58)	(\$0.61)

**3. Stock-based Employee Compensation**

The accompanying financial position and results of operations of the Company have been prepared in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees*.

The following tables illustrate the effect on the Company's net loss and net loss per share had compensation costs for the Company's stock-based incentive plans been determined in accordance with the fair value based method of accounting for stock-based compensation as prescribed by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*.

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)*

	Three months ended September 30,	
	2003	2002
Net loss, as reported	(\$27,400)	(\$32,816)
Add: Stock-based employee compensation expense included in reported net loss	822	453
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(11,341)	(11,374)
Pro forma net loss	(\$37,919)	(\$43,737)
Net loss per share amounts, basic and diluted:		
As reported	(\$0.52)	(\$0.75)
Pro forma	(\$0.72)	(\$1.00)

  

	Nine months ended September 30,	
	2003	2002
Net loss, as reported	(\$88,081)	(\$88,684)
Add: Stock-based employee compensation expense included in reported net loss	1,954	1,332
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(33,923)	(34,256)
Pro forma net loss	(\$120,050)	(\$121,608)
Net loss per share amounts, basic and diluted:		
As reported	(\$1.80)	(\$2.02)
Pro forma	(\$2.45)	(\$2.77)

For the purpose of the pro forma calculation, the fair value of each option granted from the Company's stock-based incentive plans during the three and nine months ended September 30, 2003 and 2002 was estimated on the date of grant using the Black-Scholes option-pricing model. The weighted-average fair value of the options granted during the three months ended September 30, 2003 and 2002 was \$14.43 and \$9.60, respectively. The weighted-average fair value of the options granted during the nine months ended September 30, 2003 and 2002 was \$13.96 and \$15.76, respectively. The following tables summarize the assumptions used in computing the fair value of option grants.

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)***Three months ended September 30,**

	2003	2002
Expected volatility	80%	70%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.02%-3.90%	3.98%-4.72%

**Nine months ended September 30,**

	2003	2002
Expected volatility	80%	70%
Expected lives	5 years	5 years
Dividend yield	0%	0%
Risk-free interest rate	3.01%-4.01%	3.98%-4.72%

Under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan, the Company awards shares of Restricted Stock. Restrictions on these shares generally lapse with respect to 25% of the shares every six months over approximately a two-year period. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to these awards. The amount is based on the fair market value of shares of the Company's Common Stock on the grant date of the Restricted Stock award and is expensed, on a pro rata basis, over the period that the restrictions lapse. For the three months ended September 30, 2003 and 2002, the Company recognized compensation expense related to Restricted Stock awards of \$559 and \$453, respectively. For the nine months ended September 30, 2003 and 2002, the Company recognized compensation expense related to Restricted Stock awards of \$1,691 and \$1,332, respectively.

**4. Statement of Cash Flows**

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2003 and December 31, 2002 are \$694 and \$13,490, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2002 and December 31, 2001 are \$5,904 and \$1,946, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2002 and 2001 are \$747 and \$764, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of both 2003 and 2002, the Company contributed 42,543 and 21,953 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2003 and December 31, 2002 are \$437 and \$2,013, respectively, of accrued interest income. Included in marketable

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)*

securities at September 30, 2002 and December 31, 2001 are \$2,433 and \$1,988, respectively, of accrued interest income.

**5. Inventories**

Inventories consist of raw materials and other direct and indirect costs associated with production of an intermediate for a Merck & Co., Inc. ("Merck") pediatric vaccine under a long-term manufacturing agreement.

Inventories as of September 30, 2003 and December 31, 2002 consist of the following:

	September 30, 2003	December 31, 2002
Raw materials	\$ 429	\$ 357
Work-in-process	951	261(2)
Finished products	6,318(1)	6,213(3)
	<u>\$7,698</u>	<u>\$6,831</u>

(1) Net of reserves of \$683.

(2) Net of reserves of \$32.

(3) Net of reserves of \$1,223.

**6. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses as of September 30, 2003 and December 31, 2002 consist of the following:

	September 30, 2003	December 31, 2002
Accounts payable	\$ 3,860	\$13,297
Accrued payroll and related costs	5,387	4,162
Accrued clinical trial expense	4,436	4,515
Accrued capital expenditures	335	4,322
Accrued expenses, other	1,907	1,721
Interest payable on convertible notes	5,042	2,292
	<u>\$20,967</u>	<u>\$30,309</u>

**7. Comprehensive Loss**

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)*

unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended September 30, 2003 and 2002, the components of comprehensive loss are:

	Three months ended September 30,	
	2003	2002
Net loss	(\$27,400)	(\$32,816)
Change in net unrealized gain on marketable securities	(168)	(50)
<b>Total comprehensive loss</b>	<b>(\$27,568)</b>	<b>(\$32,866)</b>

For the nine months ended September 30, 2003 and 2002, the components of comprehensive loss are:

	Nine months ended September 30,	
	2003	2002
Net loss	(\$88,081)	(\$88,684)
Change in net unrealized gain on marketable securities	(415)	(450)
<b>Total comprehensive loss</b>	<b>(\$88,496)</b>	<b>(\$89,134)</b>

**8. Collaboration Agreements*****Aventis Pharmaceuticals Inc.***

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. ("Aventis") to jointly develop and commercialize the Company's Vascular Endothelial Growth Factor ("VEGF") Trap throughout the world with the exception of Japan, where product rights remain with Regeneron. In connection with this agreement, Aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for \$45.0 million, based upon the average closing price of the Common Stock for the five consecutive trading days ending September 4, 2003.

Under the Aventis Agreement, Regeneron and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a \$25.0 million payment to the Company upon achievement of a defined clinical milestone. The Company may also receive up to \$360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States.

Under the Aventis Agreement, development expenses incurred by both companies during the term of the agreement will be funded by Aventis. Should the collaboration become profitable, Regeneron's share of the profits will be used to pay back to Aventis 50 percent of those VEGF Trap development expenses.

Aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements**

*(Unless otherwise noted, dollars in thousands, except per share data)*

obligation with respect to reimbursing Aventis, from a portion of the Company's profits, for 50 percent of the VEGF Trap development expenses will also terminate.

Revenue related to payments from Aventis is being recognized under the Substantive Milestone Method (see Note 2) in accordance with SAB 101. The up-front payment of \$80.0 million and reimbursement of Regeneron-incurred development expenses are being recognized as contract research and development revenue. Milestone payments will be recognized as research progress payments. For both the three and nine months ended September 30, 2003, the Company recognized \$2.6 million of contract research and development revenue in connection with the Aventis Agreement. At September 30, 2003, amounts receivable from Aventis totaled \$1.7 million and deferred revenue was \$79.1 million.

***Novartis Pharma AG***

In March 2003, the Company entered into a collaboration agreement (the "Novartis Agreement") with Novartis Pharma AG ("Novartis") to jointly develop and commercialize the Company's Interleukin-1 Cytokine Trap ("IL-1 Trap") throughout the world with the exception of Japan, where product rights remain with Regeneron. In connection with this agreement, Novartis made a non-refundable up-front payment of \$27.0 million and purchased \$48.0 million of newly issued unregistered shares of the Company's Common Stock. Regeneron issued 2,400,000 shares of Common Stock to Novartis in March 2003 and an additional 5,127,050 shares in May 2003 for a total of 7,527,050 shares based upon the average closing price of the Common Stock for the 20 consecutive trading days ending May 12, 2003.

Development expenses incurred during 2003 will be shared equally by the Company and Novartis. Regeneron may fund its share of 2003 development expenses through a loan (the "2003 Loan") from Novartis, which will bear interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly (3.66% at September 30, 2003). The 2003 Loan and accrued interest thereon will be forgiven should certain defined pre-clinical and clinical milestones be reached; otherwise, such amounts are payable on July 1, 2004. As of September 30, 2003, the 2003 Loan balance due Novartis, including accrued interest, totaled \$9.3 million.

After 2003, Novartis will be responsible for any additional pre-Phase III development expenses, and the companies will equally share Phase III development expenses and share promotional expenses prior to product launch. Funding for Regeneron's share of Phase III development expenses will be available through another loan (the "Post-2003 Loan") from Novartis. Also, Regeneron's share of promotional expenses after 2005 and prior to product launch may be funded through an additional loan (the "Promotion Expense Loan") from Novartis. These loans will bear interest at a rate per annum equal to the LIBOR rate plus 2.5%, compounded quarterly. The Post-2003 Loan and the Promotion Expense Loan, including accrued interest thereon, will be due five and three years, respectively, after the earlier of either the first

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements**

*(Unless otherwise noted, dollars in thousands, except per share data)*

commercial sale of an IL-1 Trap product in the United States or Europe or the effective date of termination of the agreement by Novartis.

Novartis has the right to terminate the agreement without cause with at least nine months advance notice.

The Company and Novartis will share co-promotion rights and profits on sales, if any, of the IL-1 Trap. In addition, the Company may receive up to \$275.0 million in milestone payments upon the receipt of specified regulatory approvals and the achievement of certain product revenues targets. Also, under the Novartis Agreement, the Company and Novartis each has the option to collaborate in the future on the development and commercialization of additional defined IL-1 product candidates.

Revenue related to payments from Novartis is being recognized as contract research and development revenue under the Substantive Milestone Method (see Note 2) in accordance with SAB 101. The up-front payment of \$27.0 million and reimbursement of Novartis' share of Regeneron-incurred development expenses are being recognized as contract research and development revenue. Forgiveness of the 2003 Loan and accrued interest (if forgiven as described above), and milestone payments will be recognized as research progress payments. For the three and nine months ended September 30, 2003, the Company recognized \$5.2 million and \$17.1 million, respectively, of contract research and development revenue in connection with the Novartis Agreement. At September 30, 2003, amounts receivable from Novartis totaled \$3.9 million and deferred revenue was \$22.9 million.

**9. License Agreement**

In August 2003, Merck granted the Company a non-exclusive license agreement to certain patents and patent applications which may be used in the development and commercialization of AXOKINE®. As consideration, the Company issued to Merck 109,450 newly issued unregistered shares of its Common Stock (the "Merck Shares"), valued at \$1,500 based on the fair market value of shares of the Company's Common Stock on the agreement's effective date. The agreement also requires the Company to make an additional payment to Merck upon receipt of marketing approval for a product covered by the licensed patents. In addition, the Company would be required to pay royalties, at staggered rates in the mid-single digits, based on the net sales of products covered by the licensed patents.

At any time prior to the date that Merck has the right to sell the Merck Shares under the Securities Act of 1933 (the "Sales Date"), Regeneron has the right to buy back the Merck Shares from Merck for a purchase price equal to the greater of (a) \$1,500 and (b) the lesser of (i) the fair market value of the shares and (ii) \$1,650. Unless Regeneron has previously exercised its right to buy back the Merck Shares, on the Sales Date if the fair market value of the Merck Shares (the "Market Price") is less than \$1,500, Regeneron will be required to make a cash payment to Merck equal to the difference between the

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)*

Market Price and \$1,500. Conversely, if on the Sales Date the Market Price is greater than \$1,650, Merck will be required, at its option, to either (i) make a cash payment to Regeneron equal to the difference between the Market Price and \$1,650 (the "Excess Amount") or (ii) return a number of the Merck Shares to Regeneron, calculated by dividing the Excess Amount by the fair market value of a share of the Company's Common Stock on the Sales Date. Based on the fair market value of the Company's Common Stock at September 30, 2003, the Company marked this obligation to market, resulting in the recognition of non-cash income totaling \$284 for both the three months and nine months ended September 30, 2003. Such amount has been included in investment income in the accompanying financial statements.

**10. Per Share Data**

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. For the three and nine months ended September 30, 2003 and 2002, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

<b>Three months ended September 30,</b>	<b>Net Loss, in thousands (Numerator)</b>	<b>Shares, in thousands (Denominator)</b>	<b>Per Share Amount</b>
2003:			
Basic and diluted	(\$27,400)	52,902	(\$0.52)
2002:			
Basic and diluted	(\$32,816)	43,950	(\$0.75)
<b>Nine months ended September 30,</b>	<b>Net Loss, in thousands (Numerator)</b>	<b>Shares, in thousands (Denominator)</b>	<b>Per Share Amount</b>
2003:			
Basic and diluted	(\$88,081)	48,926	(\$1.80)
2002:			
Basic and diluted	(\$88,684)	43,895	(\$2.02)

Shares issuable upon the exercise of options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)*

	Three months ended September 30,	
	2003	2002
<b>Options:</b>		
Weighted average number, in thousands	11,133	9,483
Weighted average exercise price	\$ 21.59	\$ 21.38
<b>Restricted Stock:</b>		
Weighted average number, in thousands	125	73
<b>Convertible Debt:</b>		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25
	Nine months ended September 30,	
	2003	2002
<b>Options:</b>		
Weighted average number, in thousands	11,332	9,459
Weighted average exercise price	\$ 21.44	\$ 21.43
<b>Restricted Stock:</b>		
Weighted average number, in thousands	158	89
<b>Convertible Debt:</b>		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25

**11. Segment Reporting**

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

**Research and development:** Includes all activities related to the discovery of potential therapeutics for human medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements.

**Contract manufacturing:** Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produces an intermediate for a Merck pediatric vaccine under a long-term manufacturing agreement.

The table below presents information about reported segments for the three and nine months ended September 30, 2003 and 2002.

**REGENERON PHARMACEUTICALS, INC.****Notes to Condensed Financial Statements***(Unless otherwise noted, dollars in thousands, except per share data)***Three months ended September 30, 2003**

	<b>Research &amp; Development</b>	<b>Contract Manufacturing</b>	<b>Reconciling Items</b>	<b>Total</b>
Revenues	\$ 10,882	\$ 6,510	—	\$ 17,392
Depreciation and amortization	3,395	—(1)	\$ 261	3,656
Interest expense	58	—	2,924	2,982
Net (loss) income	(27,427)	1,666	(1,639) <sup>(2)</sup>	(27,400)
Capital expenditures	2,742	—	—	2,742

**Three months ended September 30, 2002**

	<b>Research &amp; Development</b>	<b>Contract Manufacturing</b>	<b>Reconciling Items</b>	<b>Total</b>
Revenues	\$ 2,780	\$ 3,786	—	\$ 6,566
Depreciation and amortization	1,909	—(1)	\$ 261	2,170
Interest expense	6	—	3,011	3,017
Net (loss) income	(34,332)	2,149	(633) <sup>(2)</sup>	(32,816)
Capital expenditures	10,864	—	—	10,864

**Nine months ended September 30, 2003**

	<b>Research &amp; Development</b>	<b>Contract Manufacturing</b>	<b>Reconciling Items</b>	<b>Total</b>
Revenues	\$ 28,245	\$ 7,980	—	\$ 36,225
Depreciation and amortization	7,840	—(1)	\$ 783	8,623
Interest expense	66	—	8,760	8,826
Net (loss) income	(85,126)	2,211	(5,166) <sup>(2)</sup>	(88,081)
Capital expenditures	15,596	—	—	15,596
Total assets	88,543	12,067	399,891 <sup>(3)</sup>	500,501

**Nine months ended September 30, 2002**

	<b>Research &amp; Development</b>	<b>Contract Manufacturing</b>	<b>Reconciling Items</b>	<b>Total</b>
Revenues	\$ 8,215	\$ 8,861	—	\$ 17,076
Depreciation and amortization	5,623	—(1)	\$ 782	6,405
Interest expense	32	2	9,032	9,066
Net (loss) income	(91,457)	4,102	(1,329) <sup>(2)</sup>	(88,684)
Capital expenditures	23,122	35	—	23,157
Total assets	54,666	12,564	351,362 <sup>(3)</sup>	418,592

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements**

*(Unless otherwise noted, dollars in thousands, except per share data)*

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- (1) Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.
  - (2) Represents investment income, net of interest expense related to convertible notes issued in October 2001.
  - (3) Includes cash and cash equivalents, marketable securities, restricted marketable securities, prepaid expenses and other current assets, and other assets.

**12. Legal Matters**

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of the Company's officers and directors in the United States District Court for the Southern District of New York. The complaints, which purport to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. The Company's management believes that the lawsuits are without merit. The ultimate outcome of these matters cannot presently be determined. Accordingly, no provision for any liability that may result upon the resolution of these matters has been made in the accompanying financial statements.

**13. Commitments and Contingencies**

In November 2002, the Financial Accounting Standards Board issued FASB Interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, including Indirect Guarantees of Indebtedness of Others, an interpretation of SFAS Nos. 5, 57 and 107 and Rescission of FASB Interpretation No. 34*. FIN 45 clarifies the requirements of SFAS No. 5, *Accounting for Contingencies*, relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. Adoption of FIN 45 did not have a material impact on either the operating results or financial position of the Company.

The Company enters into indemnification provisions, normal and customary for companies in its industry sector, under its agreements with third parties in its ordinary course of business, typically with business partners, clinical sites, and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless, and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company's product candidates, use of such product candidates, or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification

**REGENERON PHARMACEUTICALS, INC.**

**Notes to Condensed Financial Statements**

*(Unless otherwise noted, dollars in thousands, except per share data)*

provisions is unlimited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these provisions is minimal. Accordingly, the Company has no liabilities recorded for these provisions as of September 30, 2003.

**14. Future Impact of Recently Issued Accounting Standards**

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 ("SFAS No. 150"), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 specifies that instruments within its scope embody obligations of the issuer and that the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments, (2) obligations to repurchase the issuer's equity shares by transferring assets, and (3) certain obligations to issue a variable number of shares. SFAS No. 150 defines a "freestanding financial instrument" as a financial instrument that (1) is entered into separately and apart from any of the entity's other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, SFAS No. 150 is effective immediately. For all other instruments of public companies, SFAS No. 150 went into effect at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's financial statements for the third quarter of 2003. The Financial Accounting Standards Board is expected to defer the effective date for selected provisions of SFAS No. 150, limited to mandatorily redeemable noncontrolling interests associated with finite-lived subsidiaries. The deferral of those selected provisions is not expected to have a material impact on the Company's financial statements.

## Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

### General

**Overview.** *The discussion below contains forward-looking statements that involve risks and uncertainties relating to the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible therapeutic applications of our product candidates and research programs, the timing, nature, and success of the clinical and research programs now underway or planned, and the future uses of capital and our financial needs. These statements are made by us based on management’s current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption “Factors That May Affect Future Operating Results” which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.*

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic products for the treatment of serious medical conditions. Our clinical and preclinical pipeline includes product candidates for the treatment of obesity, rheumatoid arthritis and other inflammatory conditions, cancer and related disorders, allergies, asthma, and other diseases and disorders. Developing and commercializing new medicines entails risk and significant expense. Since inception, we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to combine our strong foundation in basic scientific research and discovery-enabling technology with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that have the potential to address a variety of unmet medical needs. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. These platforms are designed to discover specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models in which a specific gene is removed (referred to as “knock-out”) or is overproduced (referred to as “transgenic”). We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Below is a summary of our leading clinical and preclinical research programs. The IL-1 Trap is being developed in collaboration with Novartis Pharma AG, and the VEGF Trap is being developed in collaboration with Aventis Pharmaceuticals Inc. We

retain sole ownership and marketing rights for AXOKINE and the IL-4/13 Trap and currently are developing them independently of any corporate partners.

- **AXOKINE®:** Acts on the brain region regulating food intake and energy expenditure and is being developed for the treatment of obesity. In March 2003, we reported data from the 12-month treatment period of our initial Phase III pivotal trial of AXOKINE. This trial enrolled approximately 2,000 patients and involved a 12-month treatment period in which subjects received daily subcutaneous self-injections of placebo or AXOKINE. The study demonstrated that subjects receiving AXOKINE experienced a greater average weight loss than those receiving placebo (6.2 lbs. vs. 2.6 lbs,  $p < .001$ ) and that a greater proportion of AXOKINE-treated subjects lost at least 5 percent of their initial body weight compared with placebo-treated subjects (25.1 percent vs. 17.6 percent,  $p < .001$ ). Although the Phase III study met its primary endpoints and many individuals achieved a medically meaningful weight loss, the average weight loss was small and limited by the development of antibodies. The study also showed that AXOKINE had a favorable safety and tolerability profile. The treatment period in this study is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. The extension phase is expected to be completed in the first quarter of 2004.

In April 2003, we announced the results of a 12-week Phase II clinical trial to assess the safety and efficacy of AXOKINE in overweight and obese individuals with type 2 diabetes mellitus. The study showed that treatment with AXOKINE resulted in statistically significant and dose-dependent weight loss, which was in line with the weight loss observed in the Phase III pivotal trial at the same 12-week time point. A 12-week open-label extension phase has also been completed.

Regeneron announced in September 2003 that we are moving forward with the Phase III development program of AXOKINE for the treatment of obesity. The announcement was made following a meeting with the United States Food and Drug Administration during which we reviewed results of the completed initial pivotal trial and our plans for future development of AXOKINE.

- **INTERLEUKIN-1 CYTOKINE TRAP (IL-1 Trap):** Protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. IL-1 is thought to play a major role in rheumatoid arthritis and other inflammatory diseases. In March 2003, we entered into an agreement with Novartis to jointly develop and commercialize the IL-1 Trap throughout the world with the exception of Japan, where product rights remain with Regeneron.

In October 2003, we announced that the IL-1 Trap demonstrated evidence of efficacy and safety in patients with rheumatoid arthritis (RA) in a Phase II dose-ranging study in approximately 200 patients. Patients treated with the highest dose, 100 milligrams of the IL-1 Trap, exhibited non-statistically significant

improvements in the primary endpoint of the trial, change in the proportion of American College of Rheumatology (ACR) 20 responses versus placebo. The IL-1 Trap also exhibited improvements in secondary endpoints of the trial. The IL-1 Trap was generally well tolerated and was not associated with any serious adverse events. We are working together with Novartis to evaluate the data from this trial and determine the best path forward for the next clinical study.

- **VEGF TRAP:** Protein-based therapeutic candidate designed to bind Vascular Endothelial Growth Factor (called VEGF, also known as Vascular Permeability Factor or VPF) and prevent its interaction with cell surface receptors. VEGF is required for the growth of blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leak. In 2001, we initiated a dose-escalation Phase I clinical trial designed to assess the safety and tolerability of the VEGF Trap in subjects with solid tumor malignancies and/or non-Hodgkin's lymphoma. This trial continues to test increasing doses of VEGF Trap delivered by subcutaneous injection as per the protocol and is expected to be completed in the first half of 2004. An additional phase of the study with VEGF Trap delivered intravenously is planned. Further studies of the VEGF Trap in cancer and as a potential treatment for diseases of the eye also are being planned.

In September 2003, we entered into a Collaboration Agreement with Aventis to jointly develop and commercialize the VEGF Trap in cancer, ophthalmology, and possibly other indications throughout the world with the exception of Japan, where product rights remain with Regeneron.

- **INTERLEUKIN-4/INTERLEUKIN-13 CYTOKINE TRAP (IL-4/13 Trap):** Protein-based product candidate designed to bind the interleukin-4 and interleukin-13 (called IL-4 and IL-13) cytokines and prevent their interaction with cell surface receptors. IL-4 and IL-13 are thought to play a major role in diseases such as asthma, allergic disorders, and other inflammatory diseases. In October 2002, we initiated a Phase I trial for the IL-4/13 Trap in adult subjects with mild to moderate asthma. This placebo-controlled, double-blind, dose escalation study is designed to assess the safety and tolerability of the IL-4/13 Trap. The trial is expected to be completed in the first quarter of 2004. We are also evaluating the potential use of the IL-4/13 Trap in other therapeutic indications.

In addition, we have formed collaborations to advance other research and development efforts. We are conducting research with The Procter & Gamble Company in muscle diseases and other fields. We are also collaborating with Medarex, Inc. to discover, develop, and commercialize certain human antibodies as therapeutics. In these research collaborations, we retain 50% of the commercialization rights.

*Discussion of Third Quarter 2003 Activities*

In July 2001, we initiated a Phase III clinical program of AXOKINE in overweight and obese subjects. The initial pivotal Phase III trial was a double-blind, randomized, placebo-controlled study that enrolled approximately 2,000 subjects at 65 sites across the United States. In March 2003, we reported data from the 12-month treatment period of the trial during which subjects received daily subcutaneous self-injections of placebo or AXOKINE at a dose of 1.0 microgram per kilogram of body weight (mcg/kg). The study demonstrated that subjects receiving AXOKINE experienced a greater average weight loss than those receiving placebo (6.2 pounds vs. 2.6 pounds,  $p < .001$ ) and that a greater proportion of AXOKINE-treated subjects lost at least 5 percent of their initial body weight compared with placebo-treated subjects (25.1 percent vs. 17.6 percent,  $p < .001$ ). AXOKINE also achieved statistically significant results in two of the three secondary endpoints, including the proportion of subjects losing at least 10% of their initial body weight. AXOKINE demonstrated a favorable safety and tolerability profile in the study. The double-blind treatment period is being followed by a twelve-month open-label extension phase, during which all study subjects receive AXOKINE. As of September 30, 2003, the average treatment period for participants in this trial was 23 months.

Although the results of the Phase III study were statistically significant, the average weight loss for the entire treatment group was small. AXOKINE-associated weight loss was limited by the development of antibodies in approximately two-thirds of the AXOKINE-treated subjects. In the patients who did not become resistant to AXOKINE treatment through the development of antibodies, the weight loss appeared in line with currently available treatments for obesity. A more complete discussion of the results of this trial is contained in our Annual Report on Form 10-K for the year ended December 31, 2002.

In April 2003, we announced the results of a 12-week Phase II clinical trial to assess the safety and efficacy of AXOKINE in 157 overweight and obese individuals with type 2 diabetes mellitus who were treated with placebo or AXOKINE at doses of 1.0 mcg/kg or 0.5 mcg/kg per day. Subjects who were treated with AXOKINE at the 1.0 mcg/kg dose with dietary counseling lost 6.5 pounds on average, while those treated with placebo and dietary counseling lost only 2.5 pounds ( $p < .01$ ). Trends toward improvements in blood glucose and other metabolic parameters were also observed during this small, short-term study. AXOKINE was generally well tolerated with no AXOKINE-related serious adverse events. Approximately 90 percent of study participants completed the 12-week study. This trial recently completed a 12-week open-label extension phase.

In this trial in patients with type 2 diabetes, approximately one-third of the subjects who were treated with the 1.0 mcg/kg dose of AXOKINE developed antibodies to AXOKINE at the twelve-week time point. In the recently completed Phase III study of AXOKINE in non-diabetic subjects, about half of AXOKINE-treated participants had developed antibodies at the 12-week time point. This lower incidence of antibodies

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observed in the Phase II study will need to be explored in a larger Phase III study in the diabetic population. In the Phase III one-year study, weight loss beyond 12 weeks appeared to be more limited in those people who developed antibodies.

In September 2003, we announced that we will move forward with the Phase III development program of AXOKINE for the treatment of obesity. This decision was made following a meeting with the FDA during which we reviewed results of the completed initial pivotal trial and our plans for future development of AXOKINE.

The remaining Phase III program is expected to consist of one-year evaluations of a broad range of overweight and obese individuals, including patients with type 2 diabetes, and several smaller and shorter studies. In total, approximately 2,300 additional people are expected to be enrolled in future trials.

Two AXOKINE trials remain ongoing. These trials, which each include approximately 300 subjects, are evaluating the safety of intermittent treatment with AXOKINE and studying maintenance of weight loss following short-term treatment regimens. Results from these trials are expected to be available in the first half of 2004. In January 2003, we announced that AXOKINE had received fast track designation from the FDA for the treatment of severely obese people who are unresponsive to, intolerant of, or unsuitable candidates for certain FDA-approved medicines for the long-term treatment of obesity. No decision has been made yet to conduct a trial that evaluates AXOKINE in this patient group.

In July 2002, we announced the initiation of a dose-ranging Phase II study of the IL-1 Trap in subjects with rheumatoid arthritis. This trial enrolled approximately 200 subjects who received weekly self-injections of one of three fixed doses of IL-1 Trap or placebo for 12 weeks, followed by 10 weeks of off-treatment follow-up. In October 2003, we announced that in this trial the IL-1 Trap demonstrated evidence of efficacy and safety. Patients treated with the highest dose, 100 milligrams of the IL-1 Trap, exhibited non-statistically significant improvements in the primary endpoint of the trial, change in the proportion of ACR 20 responses versus placebo. The IL-1 Trap also exhibited improvements in secondary endpoints of the trial. The IL-1 Trap was generally well tolerated and was not associated with any serious adverse events. We are working together with Novartis to evaluate the data from this trial and determine the best path forward for the next clinical study. The IL-1 Trap is also being evaluated for potential uses in treating other inflammatory diseases.

In March 2003, we entered into a Collaboration, License and Option Agreement with Novartis to jointly develop and commercialize the IL-1 Trap in rheumatoid arthritis and other indications throughout the world with the exception of Japan, where product rights remain with Regeneron. We and Novartis will share equally in all profits from future sales of the IL-1 Trap in North America and Europe. In other markets, Novartis will be entitled to receive 75 percent of the profits and we will be entitled to 25 percent of the profits. We may co-promote the IL-1 Trap in all territories under the agreement. As part of the agreement, Novartis purchased \$48.0 million of Regeneron's common stock

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and made a non-refundable up-front payment of \$27.0 million. The agreement is described in greater detail in the section of this report titled “Liquidity and Capital Resources”.

In November 2001, we initiated a Phase I clinical trial designed to assess the safety and tolerability of VEGF Trap in patients with solid tumor malignancies and subjects with non-Hodgkin’s lymphoma. The Phase I trial is an open-label study in subjects with advanced tumors and is evaluating the VEGF Trap in increasing dose levels. The study is being conducted at three clinical sites in the United States. This trial continues to test increasing doses of VEGF Trap delivered by subcutaneous injection as per the protocol and is expected to be completed in the first half of 2004. An additional phase of the study with VEGF Trap delivered intravenously is planned. Further studies of the VEGF Trap in cancer and as a potential treatment for diseases of the eye also are being planned.

In September 2003, we entered into a Collaboration Agreement with Aventis to jointly develop and commercialize the VEGF Trap in cancer, ophthalmology, and possibly other indications throughout the world with the exception of Japan, where product rights remain with Regeneron. We and Aventis will equally share promotion rights and profits from future sales of VEGF Trap. Aventis will fund development costs. Should the collaboration become profitable, we will pay back to Aventis 50 percent of the development costs. We will continue to manufacture clinical supplies of the VEGF Trap at our facilities in Rensselaer, New York, while Aventis will be responsible for providing commercial scale manufacturing capacity. As part of the agreement, Aventis purchased \$45.0 million of Regeneron common stock and made a non-refundable up-front payment of \$80.0 million. The agreement is described in greater detail in the section of this report titled “Liquidity and Capital Resources”.

We have developed both an IL-4 Trap and an IL-4/13 Trap, which is a single molecule that can block both interleukin-4 and interleukin-13. In October 2002, we initiated a Phase I clinical trial of a dual IL-4/13 Trap to assess the safety and tolerability of increasing dose levels in subjects with mild to moderate asthma. The Phase I trial is expected to be completed in the first quarter of 2004. We are continuing our research of IL-4 and IL-13 in other inflammatory conditions beyond asthma, which may lead to new potential indications for the IL-4/13 Trap.

A minority of all research and development programs ultimately results in commercially successful pharmaceutical products; it is not possible to predict whether any program will succeed until it actually produces a medicine that is commercially marketed for a significant period of time. In addition, in each of the areas of our independent and collaborative activities, other companies and entities are actively pursuing competitive paths toward similar objectives. The results of Regeneron’s and its collaborators’ past activities in connection with the research and development of AXOKINE, Cytokine Traps, Angiopoietins, cancer, abnormal bone growth, muscle atrophy, small molecules, and other programs or areas of research or development do not

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necessarily predict the results or success of current or future activities including, but not limited to, any additional preclinical or clinical studies. We cannot predict whether, when, or under what conditions any of our research or product candidates, including without limitation AXOKINE, IL-1 Trap, VEGF Trap, or IL-4/13 Trap will be shown to be safe or effective to treat any human condition or be approved for marketing by any regulatory agency. The delay or failure of current or future studies to demonstrate the safety or efficacy of its product candidates to treat human conditions or to be approved for marketing could have a material adverse impact on Regeneron. We discuss the risks associated with pharmaceutical drug development in the section of this report titled “Factors That May Affect Future Operating Results.”

We have not received revenue from the commercialization of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing our research and development efforts and obtaining regulatory approval from the FDA or regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies noncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2003, we had a cumulative loss of \$512.2 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Our activities may expand over time and may require additional resources and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the timing of certain expenses and on the progress of our research and development efforts.

### **Change in Accounting Method**

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101). During the third quarter of 2003, we elected to change the method we use to recognize revenue under SAB 101 related to non-refundable collaborator payments, including up-front licensing payments, payments for development activities, and research progress (milestone) payments, to the Substantive Milestone Method, adopted retroactively to January 1, 2003. Under this method, we recognize revenue from non-refundable up-front license payments, not tied to achieving a specific performance milestone, ratably over the period over which we are obligated to perform services. Payments for development activities are recognized as revenue as earned, ratably over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, provided there is no future service

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obligation associated with that milestone. Previously, we had recognized revenue from non-refundable collaborator payments based on the percentage of costs incurred to date, estimated costs to complete, and total expected contract revenue. However, the revenue recognized was limited to the amount of non-refundable payments received. The change in accounting method was made because we believe that it better reflects the substance of our collaborative agreements and is more consistent with current practices in the biotechnology industry. The impact of the adoption of this new revenue recognition method was to increase our revenue and reduce our net loss by \$1.5 million, or \$0.03 per share, in the third quarter of 2003, and to decrease our revenue and increase our net loss by \$0.3 million, or \$0.01 per share, for the nine months ended September 30, 2003. There is no impact on our financial results for any period prior to January 1, 2003. Our operating results for the first two quarters of 2003 have been restated in accordance with the new revenue recognition policy.

### **Results of Operations**

*Three months ended September 30, 2003 and 2002.* Our total revenue increased to \$17.4 million for the third quarter of 2003 from \$6.6 million for the same period of 2002. Contract research and development revenue increased to \$10.9 million for the third quarter of 2003 from \$2.8 million for the same period of 2002, resulting primarily from the recognition of \$7.8 million of revenue related to our collaboration with Novartis on the IL-1 Trap, which began in the first quarter of 2003, and our collaboration with Aventis on the VEGF Trap, which began in the third quarter of 2003. We recognize revenue in connection with the collaborations in accordance with SAB 101. In addition, we recognized \$2.7 million and \$2.6 million of contract research and development revenue from Procter & Gamble in the third quarter of 2003 and 2002, respectively, in connection with our long-term collaboration agreement. Contract manufacturing revenue, related to our long-term agreement with Merck & Co., Inc. to manufacture a vaccine intermediate at our Rensselaer facility, increased to \$6.5 million for the third quarter of 2003 from \$3.8 million for the same period of 2002, because we shipped more product to Merck during the third quarter of 2003 than in the corresponding period of 2002. We recognize contract manufacturing revenue and the related manufacturing expense as product is accepted by and shipped to Merck.

Our total operating expenses increased to \$43.1 million for the third quarter of 2003 from \$38.7 million for the same period of 2002. Research and development expenses increased to \$34.7 million in the third quarter of 2003 from \$34.3 million for the comparable period of 2002 as increased development expenses for the IL-1 Trap and VEGF Trap in the third quarter of 2003 were offset in part by a decline in development expenses related to the AXOKINE program. Research and development expenses were 80% of total operating expenses in the third quarter of 2003, compared with 89% for the same period of 2002. Contract manufacturing expenses related to our long-term agreement with Merck increased to \$4.8 million for the third quarter of 2003 from \$1.6 million for the same period of 2002, because the Company shipped more product to Merck during the quarter. General and administrative expenses increased to \$3.6 million

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in the third quarter of 2003 from \$2.8 million for the same period of 2002, due primarily to increased administrative costs to support the Company's expanding development pipeline, higher insurance costs, and expenses for external service providers.

Investment income decreased to \$1.3 million for the third quarter of 2003 from \$2.4 million for the same period of 2002 due to lower effective interest rates on investment securities in 2003 and lower levels of interest-bearing investments during most of the third quarter of 2003 as the Company funded its operations. Interest expense was \$3.0 million for the both the third quarter of 2003 and 2002. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Our net loss for the third quarter of 2003 was \$27.4 million, or \$0.52 per share (basic and diluted), compared with a net loss of \$32.8 million, or \$0.75 per share (basic and diluted), for the same period of 2002.

*Nine months ended September 30, 2003 and 2002.* Our total revenue increased to \$36.2 million for the nine months ended September 30, 2003 from \$17.1 million for the same period in 2002. Contract research and development revenue increased to \$28.2 million for the nine months ended September 30, 2003 from \$8.2 million for the same period of 2002, resulting primarily from the recognition of \$19.7 million of revenue related to our collaborations with Novartis on the IL-1 Trap and Aventis on the VEGF Trap. We recognize revenue in connection with the collaborations in accordance with SAB 101. In addition, we recognized \$7.9 million of contract research and development revenue from Procter & Gamble in the first nine months of both 2003 and 2002 in connection with our long-term collaboration agreement. Contract manufacturing revenue, related to our long-term agreement with Merck, decreased to \$8.0 million for the first nine months of 2003 from \$8.9 million for the same period of 2002, due primarily to the receipt of a non-recurring \$1.0 million payment in the third quarter of 2002. This decrease was partly offset because we shipped more product to Merck in the first nine months of 2003 compared with the same period of 2002.

Our total operating expenses increased to \$119.1 million for the nine months ended September 30, 2003 from \$104.4 million for the same period of 2002. Research and development expenses increased to \$102.8 million for the first nine months of 2003 from \$90.5 million for the comparable period of 2002, due primarily to higher expenses associated with the Company's development programs for the IL-1 Trap for the treatment of rheumatoid arthritis and VEGF Trap for the treatment of cancer. Research and development expenses were 86% of total operating expenses in the first nine months of 2003, compared with 87% for the same period of 2002. Contract manufacturing expenses related to our long-term agreement with Merck increased to \$5.8 million for the nine months ended September 30, 2003 from \$4.8 million for the same period of 2002, because we shipped more product to Merck in 2003 and the costs to manufacture the vaccine intermediate increased slightly compared with the prior year period. General and administrative expenses increased to \$10.5 million for the first nine months of 2003 from \$9.2 million for the same period of 2002, due primarily to increased administrative costs

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to support the Company's expanding development pipeline, higher insurance costs, and expenses for external service providers.

Investment income decreased to \$3.6 million for the nine months ended September 30, 2003 from \$7.7 million for the same period of 2002 due to lower effective interest rates on investment securities in 2003 and lower levels of interest-bearing investments during most of the period through September 30, 2003 as the Company funded its operations. Interest expense declined slightly to \$8.8 million for the first nine months of 2003 from \$9.1 million for the same period of 2002. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Our net loss for the nine months ended September 30, 2003 was \$88.1 million, or \$1.80 per share (basic and diluted), compared with a net loss of \$88.7 million, or \$2.02 per share (basic and diluted), for the same period of 2002.

### **Liquidity and Capital Resources**

Since our inception in 1988, we have financed our operations primarily through offerings of equity securities, a private placement of convertible debt, revenue earned under our agreements with Amgen Inc., Sumitomo Chemical Co., Ltd., Sumitomo Pharmaceuticals Company, Ltd., Merck, Procter & Gamble, Novartis, and Aventis, and investment income.

In September 2003, the Company entered into a collaboration agreement with Aventis to jointly develop and commercialize the VEGF Trap. Aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for \$45.0 million.

Under the collaboration agreement, we and Aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap. Aventis has agreed to make a \$25.0 million payment to us upon achievement of a clinical milestone. We may also receive up to \$360.0 million in additional milestone payments upon receipt of specified marketing approvals for up to eight VEGF Trap indications in Europe or the United States. Regeneron has agreed to continue to manufacture clinical supplies of the VEGF Trap at our plant in Rensselaer, New York. Aventis has agreed to be responsible for providing commercial scale manufacturing capacity for the VEGF Trap.

Under the collaboration agreement, development expenses incurred by both companies during the term of the agreement will be funded by Aventis. Should the collaboration become profitable, our share of the profits will be used to pay back to Aventis 50 percent of those VEGF Trap development expenses. At September 30, 2003, \$1.7 million was receivable from Aventis for development expenses incurred by Regeneron during the period from the effective date of the collaboration through September 30, 2003.

Aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, our

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obligation with respect to reimbursing Aventis, from a portion of our profits, for 50 percent of the VEGF Trap development expenses will also terminate.

In March 2003, we entered into a collaboration agreement with Novartis to jointly develop and commercialize the IL-1 Trap. Novartis made a non-refundable up-front payment of \$27.0 million and purchased 7,527,050 newly issued unregistered shares of our common stock for \$48.0 million.

Development expenses incurred during 2003 will be shared equally by Regeneron and Novartis. We may fund our share of 2003 expenses through a loan from Novartis that will be forgiven, together with accrued interest, should certain preclinical and clinical milestones be reached and is otherwise payable on July 1, 2004. As of September 30, 2003, we have drawn \$9.2 million against this loan facility. In addition, at September 30, 2003, \$3.9 million was receivable from Novartis for their share of IL-1 Trap development expenses incurred by Regeneron during the third quarter of 2003.

After 2003, Novartis will be responsible for any additional pre-Phase III development expenses, and the companies will share Phase III development expenses and pre-launch expenses. Our share of these expenses may be funded through two additional loans from Novartis. The loan and accrued interest for our share of Phase III development expenses is repayable in full five years after the initial product launch of the IL-1 Trap or five years after termination of Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. The loan and accrued interest for our share of pre-launch expenses is repayable in full three years after the initial product launch of the IL-1 Trap or three years after termination of Novartis' rights to the IL-1 Trap under the agreement, whichever occurs first. Novartis has the right to terminate the collaboration agreement without cause with at least nine months advance notice.

We and Novartis will share co-promotion rights and profit on sales, if any, of the IL-1 Trap. In addition, we may receive up to \$275.0 million in milestone payments upon receipt of specified regulatory approvals in the United States and the European Union and the achievement of certain product revenues targets. Under the agreement, each company also has the right to elect to collaborate on the development and commercialization of certain other preclinical/early development IL-1 antagonists that we and Novartis currently are developing independently. Regeneron will continue to manufacture clinical supplies of the IL-1 Trap at our Rensselaer plant. Novartis will be responsible for providing commercial scale manufacturing capacity for the IL-1 Trap.

Under a long-term collaboration agreement, Procter & Gamble provides funding through December 2005 of \$2.5 million per quarter, plus adjustments for inflation, in support of our research efforts.

At September 30, 2003, we had \$391.1 million in cash, cash equivalents, marketable securities, and restricted marketable securities. We have no off-balance sheet financing arrangements and do not guarantee the obligations of any other entity. As of September 30, 2003, we had no established banking arrangements through which we

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could obtain short-term financing or a line of credit. We may seek additional funding through, among other things, future collaboration agreements and public or private financing. We cannot assure you that additional financing will be available to us or, if available, that it will be available on acceptable terms.

Our additions to property, plant, and equipment totaled \$15.6 million and \$23.2 million for the first nine months of 2003 and 2002, respectively.

We expect to incur substantial funding requirements for, among other things, research and development activities (including preclinical and clinical testing), expansion and validation of manufacturing facilities, and the acquisition of equipment. We currently anticipate that for the remainder of 2003, approximately 40-60% of our expenditures will be directed toward the preclinical and clinical development of product candidates, including AXOKINE, IL-1 Trap, VEGF Trap, and IL-4/13 Trap; approximately 5-15% of our expenditures will be invested in expansion of our manufacturing facilities; approximately 10-20% of our expenditures will cover our basic research activities; approximately 5-15% of our expenditures will be directed toward the continued development of our novel technology platforms, including potential efforts to commercialize these technologies; and the remainder of our expenditures will be for general corporate purposes, including working capital. For the remainder of 2003, we expect to incur approximately \$5 million in capital expenditures for our expanded manufacturing and research and development activities.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our drug candidates, and the continuation, extent, and success of any collaborative research arrangements (including those with Procter & Gamble, Novartis, Aventis, Medarex, and Emisphere Technologies, Inc.). Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above.

We believe that our existing capital resources will enable us to meet operating needs through at least the end of 2005. However, this is a forward-looking statement

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based on our current operating plan, and we cannot assure you that there will be no change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

### **Future Impact of Recently Issued Accounting Standards**

In May 2003, the Financial Accounting Standards Board issued Statement No. 150 ("SFAS No. 150"), *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 specifies that instruments within its scope embody obligations of the issuer and that, therefore, the issuer must classify them as liabilities. SFAS No. 150 requires issuers to classify as liabilities the following three types of freestanding financial instruments: (1) mandatorily redeemable financial instruments; (2) obligations to repurchase the issuer's equity shares by transferring assets and (3) certain obligations to issue a variable number of shares. SFAS No. 150 defines a "freestanding financial instrument" as a financial instrument that (1) is entered into separately and apart from any of the entity's other financial instruments or equity transactions or (2) is entered into in conjunction with some other transaction and can be legally detached and exercised on a separate basis. For all financial instruments entered into or modified after May 31, 2003, SFAS No. 150 is effective immediately. For all other instruments of public companies, SFAS No. 150 went into effect at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on our financial statements for the third quarter of 2003. The Financial Accounting Standards Board is expected to defer the effective date for selected provisions of SFAS No. 150, limited to mandatorily redeemable noncontrolling interests associated with finite-lived subsidiaries. The deferral of those selected provisions is not expected to have a material impact on our financial statements.

### **Factors That May Affect Future Operating Results**

We caution shareholders and potential investors that the following important factors, among others, in some cases have affected, and in the future could affect, our actual results and could cause our actual results to differ materially from those expressed

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in any forward-looking statements made by, or on behalf of, us. The statements under this caption are intended to serve as cautionary statements within the meaning of the Private Securities Litigation Reform Act of 1995. The following information is not intended to limit in any way the characterization of other statements or information under other captions as cautionary statements for such purpose:

- Delay, difficulty, or failure of a clinical trial of any of our product candidates, including clinical trials of our product candidates AXOKINE, VEGF Trap, and the IL-1 Trap. If either or both of these product candidates fail to advance in the clinic, our business will be severely harmed and our stock price will be adversely affected. A clinical trial can fail or be delayed as a result of many causes, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may also fail because it did not include a sufficient number of patients to detect the endpoint being measured. For example, the pending trials studying the maintenance of weight loss following short-term treatment regimens with AXOKINE may not have enrolled enough patients to detect statistically significant differences between patients treated with AXOKINE and those taking placebo following the post-treatment maintenance periods. These trials were designed before we had access to the data from the recently completed Phase III trial, which demonstrated that the magnitude of the average difference in weight loss observed between all AXOKINE-treated subjects and those taking placebo was small.
- In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our pharmaceutical candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune type" disease. Whether antibodies will be created can often not be predicted from preclinical experiments and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been successfully completed. Subjects who have received AXOKINE and the IL-1 Trap in clinical trials have developed antibodies.
- Delay, difficulty, or failure in obtaining regulatory approval for our products, including delays or difficulties in development because of insufficient proof of safety or efficacy or the failure to manufacture product candidates in accordance with FDA requirements.

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- Delay, difficulty, or failure of our research and development programs to produce product candidates that are scientifically or commercially appropriate for further development by us or others.
- Cancellation or termination of material collaborative or licensing agreements (including in particular, but not limited to, our agreements with Novartis, Aventis, and Procter & Gamble) and the resulting loss of funding and development and manufacturing support for our product candidates could have a material adverse effect on us and our operations.
- Increased and irregular costs of development, manufacture, regulatory approval, sales, and marketing associated with the introduction of products in the late stage of development.
- Competitive or market factors that may cause use of our products to be limited or otherwise fail to achieve broad acceptance.
- The ability to obtain, maintain, and prosecute intellectual property rights and the cost of acquiring in-process technology and other necessary intellectual property rights, either by license, collaboration, or purchase of another entity.
- Difficulties or high costs of obtaining adequate financing to fund the cost of developing and manufacturing product candidates through public or private offerings or collaborative arrangements.
- Amount and rate of growth of our general and administrative expenses, and the impact of unusual charges resulting from our ongoing evaluation of our business strategies and organizational structure.
- Failure of corporate partners to develop or commercialize successfully our products or to retain and expand the markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies which may arise between our corporate partners and us.
- Delays or difficulties in developing and acquiring production technology and technical and managerial personnel to manufacture novel biotechnology products in commercial quantities at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.
- Difficulties in manufacturing sufficient amounts of our product candidates suitable for clinical testing or commercialization. Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to

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support large scale clinical testing of our product candidates, including AXOKINE, IL-1 Trap, VEGF Trap, and IL-4/13 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates. For example, AXOKINE currently is formulated for delivery in single use vials. We are in the process of developing a formulation that may be used in multiple use vials. If we are unable to develop this multiple use vial formulation, potential future AXOKINE sales and profitability may be limited.

- Difficulties in obtaining key raw materials and supplies for the manufacture of our product candidates.
- Failure of service providers upon whom we rely to carry out our clinical development programs, such as contract research organizations and third parties who fill and label our clinical supplies, to perform their contractual responsibilities. These failures could lead to delays in our clinical development programs.
- The costs and other effects of legal and administrative cases and proceedings (whether civil litigation, such as the pending shareholder class action lawsuits, product liability, intellectual property, commercial, employment-related, or environmental claims, or criminal litigation), settlements, and investigations could result in losses to the Company that severely harm our business.
- The issuance and use of patents and proprietary technology by us and our competitors, including the possible negative effect on our ability to develop, manufacture, and sell our products in circumstances where we are unable to obtain licenses to patents which may be required for our products.
- Underutilization of our existing or new manufacturing facilities or of any facility expansions, resulting in inefficiencies and higher costs; start-up costs, inefficiencies, delays, and increased depreciation costs in connection with the start of production in new plants and expansions.
- Failure to have sufficient manufacturing capacity to make clinical supplies or commercial product in a timely and cost-competitive manner. Insufficient manufacturing capacity could delay clinical trials or limit commercial sale of marketed products.
- Health care reform, including reductions or changes in reimbursement available for prescription medications or other reforms.
- Difficulties in attracting and retaining key personnel, especially in areas such as manufacturing, sales, and marketing.

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As our scientific efforts lead to potentially promising new directions, both outside of recombinant protein therapies and into conditions or diseases outside of our current areas of experience and expertise, we will require additional internal expertise or external collaborations in areas in which we currently do not have substantial resources and personnel.

Other parties could allege to have blocking patents covering any of our product candidates in clinical and/or preclinical development. For example, we are aware of certain United States and foreign patents held by third parties relating to particular IL-4 and IL-13 receptors.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing one or more of our product candidates, which could severely harm our business.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay license fees or royalties to take into account patent rights of third parties.

### **Item 3. Quantitative and Qualitative Disclosure About Market Risk.**

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent change in interest rates would result in an approximately \$0.1 million change in the fair market value of our investment portfolio at September 30, 2003.

### **Item 4. Controls and Procedures**

(a) Disclosure Controls and Procedures. Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this report. Based upon the evaluation, our President and Chief Executive Officer along with our Chief Financial Officer concluded that, as of the end of such period, our disclosure

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controls and procedures are effective in timely alerting them to material information relating to Regeneron required to be included in our reports filed or submitted under the Exchange Act.

(b) Internal Control over Financial Reporting. There have not been any changes in our internal controls over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

In May 2003, securities class action lawsuits were commenced against Regeneron and certain of its officers and directors in the United States District Court for the Southern District of New York. The complaints, which purport to be brought on behalf of a class consisting of investors in the Company's publicly traded securities between March 28, 2000 and March 30, 2003, allege that the defendants misstated or omitted material information concerning the safety and efficacy of AXOKINE, in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Damages are sought in an unspecified amount. We believe that the lawsuits are without merit.

From time to time Regeneron is a party to other legal proceedings in the course of its business. We do not expect such other legal proceedings to have a material adverse effect on our business or financial condition.

**Item 6. Exhibits and Reports on Form 8-K**

(a) Exhibits

- 10.26\* - Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
- 10.27 - Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
- 10.28\* - Non-Exclusive Patent License Agreement, effective as of August 18, 2003, by and between Merck & Co., Inc. and Regeneron Pharmaceuticals, Inc.
- 18.1 - Independent Accountant's Preferability Letter Regarding a Change in Accounting Principle
- 31 - Certification of CEO and CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
- 32 - Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

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\* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

### (b) Reports

Form 8-K, filed September 9, 2003: On September 8, 2003, we issued a press release announcing that we had entered into a global (excluding Japan) agreement with Aventis to jointly develop and commercialize the VEGF Trap.

Form 8-K, filed October 8, 2003: On October 7, 2003, we issued a press release reporting results of our IL-1 Trap Phase II dose-ranging study in patients with rheumatoid arthritis.

Form 8-K, filed October 31, 2003: On October 30, 2003, we issued a press release announcing our third quarter 2003 financial and operating results.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 12, 2003

Regeneron Pharmaceuticals, Inc.

By: /s/ Murray A. Goldberg

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Murray A. Goldberg  
Senior Vice President, Finance & Administration, Chief Financial  
Officer, Treasurer, and Assistant Secretary

COLLABORATION AGREEMENT

By and Between

AVENTIS PHARMACEUTICALS INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of September 5, 2003

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COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (“Agreement”), dated as of September 5, 2003 (the “Effective Date”), is by and between AVENTIS PHARMACEUTICALS INC., a corporation organized under the laws of Delaware and having a principal place of business at 200 Crossing Boulevard, Bridgewater, New Jersey 08807 (“Aventis”), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 (“Regeneron”) (with each of Aventis and Regeneron referred to herein individually as a “Party” and collectively as the “Parties”).

WHEREAS, Regeneron has developed certain VEGF inhibitor molecules that are in clinical and pre-clinical trials referred to herein as VEGF Trap Products, and Regeneron intends to Develop and Commercialize VEGF Trap Products in the Territory;

WHEREAS, Aventis and its Affiliates possess expertise in Developing, manufacturing and Commercializing pharmaceutical products and have in place large and experienced teams to conduct these activities; and

WHEREAS, Regeneron and Aventis desire to collaborate on the Development and Commercialization of all VEGF Trap Products and other VEGF Products in the Territory as set forth herein (the “Collaboration”).

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**ARTICLE 1  
DEFINITIONS**

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 “Acquisition Proposal” shall have the meaning set forth in Section 20.16(c).

1.2 “Additional Major Market Country” shall mean any country in the Territory, other than the Major Market Countries referred to in clause (i) of the definition thereof and the Co-Marketing Countries, in which Net Sales in the immediately prior Contract Year were [\*\*\*\*\*] or more of aggregate Net Sales in the Territory (excluding Co-Marketing Countries) and such designation shall remain effective from and after the determination of such Net Sales amount; provided, however, that a country shall not be deemed an Additional Major Market Country if, at the time that Net Sales in such country in a given Contract Year first exceed [\*\*\*\*\*] of

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aggregate Net Sales in the Territory (excluding Co-Marketing Countries), the Parties mutually agree.

1.3 “Adverse Reaction Reports” shall mean an adverse event or adverse drug reaction as defined (i) in the ICH E2A document, (ii) in any clinical safety reports, as referenced in 21 C.F.R. 312.32 (as may be amended from time to time), or (iii) any international equivalent definitions used by Regulatory Authorities in the Territory. The definition will be considered updated as these documents are officially amended by the ICH and applicable Regulatory Authorities to ensure compliance with regulatory reporting requirements.

1.4 “Affiliate” shall mean, with respect to any Person, any other Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Aventis or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates of Aventis or any of its Affiliates.

1.5 “Agreement” shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.

1.6 “Alliance Manager” shall have the meaning set forth in Section 3.11.

1.7 “Alternative Supplier” shall have the meaning set forth in Section 8.5.

1.8 “Ancillary Agreement” shall mean each other agreement referred to herein entered into or to be entered into between the Parties to the extent expressly identified herein as an Ancillary Agreement.

1.9 “Anticipated First Commercial Sale” shall mean, with respect to a VEGF Product, the date agreed upon by the Parties in advance as the expected date of First Commercial Sale of such VEGF Product in any Therapeutic Area in a country.

1.10 “Approval” shall mean, with respect to each VEGF Product, any approval (including Pricing Approvals), registration, license or authorization from any Regulatory

Authority required for the testing, manufacture, Development, Commercialization, sale, storage or transport of, or expanded labeling for, such VEGF Product in any country, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.

1.11 "Aventis" shall have the meaning set forth in the introductory paragraph.

1.12 "Aventis Indemnitees" shall have the meaning set forth in Section 17.1(b).

1.13 "Aventis Intellectual Property" shall mean the Aventis Patent Rights and any Know-How of Aventis or any of its Affiliates.

1.14 "Aventis Patent Rights" shall mean those Patent Rights which are now or hereafter during the Term owned by, licensed to, or otherwise held by Aventis or any of its Affiliates (other than pursuant to this Agreement) with the right to license or sublicense the same and which include at least one claim which would be infringed by the manufacture, use, sale, offer for sale or import of any VEGF Product.

1.15 "Aventis Sole Inventions" shall have the meaning set forth in Section 12.1(a).

1.16 "Aventis Trademarks" shall have the meaning set forth in Section 11.3.

1.17 "Aventis VEGF Products" shall mean all VEGF Products which are now or hereafter during the Term owned by, licensed to, or otherwise held by, Aventis or any of its Affiliates (other than pursuant to this Agreement) with the right to license or sublicense the same.

1.18 [\*\*\*\*\*]  
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1.19 "BLA" shall mean, with respect to each VEGF Product, a biologics license application filed with respect to such VEGF Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

1.20 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.

1.21 "Change of Control" shall mean, with respect to Regeneron, any of the following events: (i) any Person is or becomes the "beneficial owner" (as such term is used in Sections 12(d) and 13(d) of the Securities Exchange Act of 1934, as amended, except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all classes of capital stock then outstanding of Regeneron normally entitled to vote in elections of directors; (ii) Regeneron consolidates

with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into Regeneron, other than (A) a merger or consolidation which would result in the voting securities of Regeneron outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of Regeneron or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of Regeneron (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of Regeneron representing a majority of the combined voting power of Regeneron's then outstanding securities; or (iii) Regeneron conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly-owned Affiliate of such Person.

1.22 "Class A Stock" shall mean the Class A Stock of Regeneron, par value \$0.001 per share.

1.23 "Clinical Supply Cost" shall mean (i) the Manufacturing Cost of Clinical Supply Requirements, as set forth in Schedule 1.101, and (ii) the Out-of-Pocket Cost for purchasing, or Manufacturing Cost to manufacture, as the case may be, comparator agent or placebo requirements.

1.24 "Clinical Supply Requirements" shall mean, with respect to a VEGF Product, the quantities of such VEGF Product which are required by a Party or the Parties (i) for Development, including the conduct of pre-clinical studies and Clinical Trials in connection with a Co-Development Plan in order to obtain Approval of such VEGF Product in any country in the Territory and quantities of such VEGF Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in any country in the Territory or (ii) for any Non-Approval Trial.

1.25 "Clinical Trial" shall mean any clinical trial conducted for the purpose of or which results in obtaining data to support or be included in a Registration Filing, including any clinical trial conducted or sponsored by a Party's medical affairs department which is referenced in a BLA solely in connection with an integrated safety database and [\*\*\*\*\*].

1.26 "Co-Commercialize" or "Co-Commercialization" shall mean the act of Co-Promoting in a Co-Commercialization Country.

1.27 "Co-Commercialization Country" shall mean each Co-Promotion Country in which Regeneron has elected to Co-Promote and each Major Market Country irrespective of whether Regeneron has elected to Co-Promote in such Major Market Country.

1.28 “Co-Development” shall mean the joint Development of VEGF Products by the Parties, as described herein, and “Co-Develop” shall have a corresponding meaning.

1.29 “Co-Development Budget” shall mean the annual budget(s) approved by the Joint Steering Committee included in the Co-Development Plan or the Initial Co-Development Plan.

1.30 “Co-Development Plan” shall mean the annual Co-Development plan for the VEGF Products approved by the Joint Steering Committee, including the related Co-Development Budget.

1.31 “COGS” or “Cost of Goods Sold” shall mean the Manufacturing Cost of VEGF Products sold in the Major Market Countries as set forth in Schedule 1.101.

1.32 “Collaboration” shall have the meaning set forth in the recitals.

1.33 “Collaboration Purpose” shall have the meaning set forth in Section 3.1(b).

1.34 “Co-Market” or “Co-Marketing” shall mean the separate marketing and sale in a Co-Marketing Country of VEGF Products under separate and distinct trademarks.

1.35 “Co-Marketing Country” shall mean with respect to each VEGF Product, each country in the Territory in which Co-Promotion is not permitted under local Law for such VEGF Product, but in which Co-Marketing is permitted under local Law for such VEGF Product and where Regeneron has elected to Co-Market such VEGF Product in such country.

1.36 “Commercial Supply Requirements” shall mean, with respect to each VEGF Product, quantities of such VEGF Product as are required by a Party or the Parties to fulfill such Party’s or Parties’ requirements for commercial sales and product sampling with respect to such VEGF Product in the Territory or any country in the Territory, as the case may be.

1.37 “Commercialize” or “Commercialization” shall mean any and all activities directed to marketing (including activities the costs and expenses of which constitute Pre-Launch Marketing Expenses), promoting, detailing, distributing, importing, commercializing, offering for sale, having sold and/or selling a VEGF Product, including sampling and conducting Non-Approval Trials.

1.38 “Commercially Reasonable Efforts” shall mean, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be consistent with the Collaboration Purpose and substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it, which

product is at a similar stage in its development or product life and is of similar market potential. Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitive factors. It is anticipated that the level of effort will change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the profit sharing nor other payments made or required to be made hereunder shall be factors weighed (that is, a Party may not apply lesser resources or efforts in support of a VEGF Product because it must share profits from sales or make any other payments hereunder).

1.39 "Committee" means any of the JSC, JDC or JCC, each as defined in this Article 1 and described in Article 3 (together with any Joint Sub-Committee or other committee contemplated hereby or established in accordance with this Agreement or any Ancillary Agreement).

1.40 "Common Stock" shall mean the common stock of Regeneron, par value \$0.001 per share.

1.41 "Consolidated Net Profit/Loss Report" shall mean a consolidated quarterly report prepared by Aventis setting forth in reasonable detail (a) Net Sales for each Major Market Country, COGS and Shared Promotion Expenses incurred by each Party, and the Major Market Profit Split for such quarter, calculated in accordance with Schedule 1, (b) [\*\*\*\*\*], (c) Net Sales for each Rest of World Country and the Rest of World Profit Split for such quarter, calculated in accordance with Schedule 1, (d) with respect to each Rest of World Country that is also a Co-Commercialization Country, Regeneron's Sales Force Cost and Regeneron's Medical Affairs Cost for such quarter, (e) Development Costs incurred by Regeneron and Development Costs incurred by Aventis for such calendar quarter, identified separately, and (f) the Quarterly True-Up owed by a Party to the other Party, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 1.

1.42 "Contract Sales Force" shall mean the services of sales representatives employed by a Third Party.

1.43 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2003, and each succeeding twelve (12) month period thereafter during the Term.

1.44 "Controlling Party" shall mean Regeneron with respect to the filing, prosecution and maintenance of a Joint Patent Right that primarily claims a Regeneron VEGF Product (or the making or use thereof), and Aventis in the case of all other Joint Patent Rights.

1.45 “Co-Promote” or “Co-Promotion” shall mean the joint marketing and promotion of VEGF Products by the Parties (or their respective Affiliates) under the same trademark in a Co-Commercialization Country pursuant to the applicable Country Co-Commercialization Plan.

1.46 “Co-Promotion Country” shall mean any country included in the Territory other than countries where Co-Promotion is not permitted by Law.

1.47 “Country Co-Commercialization Budget” shall mean the annual budget(s) included in a Country Co-Commercialization Plan for a particular Co-Commercialization Country.

1.48 “Country Co-Commercialization Plan” shall mean the plan(s), including the related Country Co-Commercialization Budget, developed by the applicable Joint Country Commercialization Sub-Committee for each VEGF Product in a particular Co-Commercialization Country.

1.49 “Country Co-Commercialization Report” shall mean a written report summarizing the marketing and promotional activities undertaken by a Party (or its relevant local Affiliates) during the previous quarter in connection with the applicable Country Co-Commercialization Plan, together with a detailed project-level statement of Shared Promotion Expenses incurred by such Party during such quarter in such Co-Commercialization Country, including any necessary adjustments for previous quarters.

1.50 “CPI” shall mean the U.S. Department of Labor’s Consumer Price Index for All Urban Consumers or, for Major Market Countries outside the U.S., such other local inflation measure or rate agreed upon by the Parties.

1.51 “Damages” shall have the meaning set forth in Section 17.1(a).

1.52 “Default Interest Rate” shall have the meaning set forth in Section 9.8.

1.53 “Develop” or “Development” shall mean (a) activities directly and specifically relating to the pre-clinical and clinical drug development of a VEGF Product, including, without limitation, test method development and stability testing, assay development, toxicology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development, pharmacokinetic studies, Clinical Trials (including research to design Clinical Trials and develop target product profiles), regulatory affairs, drug safety surveillance activities, and Approvals, (b) any other research and development activities with respect to a VEGF Product and (c) any pre-launch marketing activities (including, without limitation, market research and analysis, and health economics) performed prior to First Commercial Sale of such VEGF Product, except for activities the costs and expenses of which constitute Pre-Launch Marketing Expenses.

1.54 “Development Balance” shall have the meaning set forth in Schedule 1.

1.55 "Development Costs" shall mean, for all Development activities, including Clinical Trials, performed after the Effective Date in accordance with the Co-Development Plan:

(a) all Out-of-Pocket Costs;

(b) the Development FTE Costs of such Clinical Trials or Development activities;

(c) the Clinical Supply Costs;

(d) the costs and expenses incurred in connection with formulation development, manufacturing process development, manufacturing scale-up, start-up, and validation, stability testing and quality assurance/quality control development (in each case, to the extent not included in COGS); and

(e) any other costs or expenses specifically identified and included in the applicable Co-Development Budget.

For clarity, it is the intent of the Parties that costs included in the foregoing will not be unfairly allocated to the VEGF Products (to the extent that any Development Cost is attributable, in part, to products or activities other than the VEGF Products).

1.56 "Development FTE Cost" shall mean, for all Clinical Trials or Development activities performed in accordance with the Co-Development Plan, including regulatory activities, the product of (a) the number of FTEs required for such Clinical Trial or activity as set forth in the approved Co-Development Plan and Co-Development Budget and (b) the Development FTE Rate.

1.57 "Development FTE Rate" shall mean [\*\*\*\*\*] in Contract Year 2003, such amount to be adjusted as of January 1, 2004 and annually thereafter by the percentage increase or decrease, if any, in the CPI since the Effective Date or the latest adjustment hereunder, whichever is later.

1.58 "Development Payment" shall have the meaning set forth in Schedule 1.

1.59 "Distributor" shall mean any Third Party contractually engaged by a Party to distribute the VEGF Products in a Rest of World Country.

1.60 "Effective Date" shall have the meaning set forth in the introductory paragraph.

1.61 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

1.62 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer or Chief Operating Officer of Aventis.

1.63 “Existing Facility” shall mean, [\*\*\*\*\*].

1.64 “Existing Licenses” shall mean the agreements listed in Part A of Schedule 3.

1.65 “Expert Panel” shall have the meaning set forth in Section 10.4.

1.66 “FDA” shall mean the United States Food and Drug Administration and any successor agency thereto.

1.67 “Finished VEGF Product” shall mean VEGF Product in its finished, labeled and packaged form, ready for sale to the market.

1.68 “First Commercial Sale” shall mean the first sale of any VEGF Product, following receipt of Marketing Approval, by a Party or one of its Affiliates, sublicensees or Distributors to a Third Party in the relevant country in the Territory, as the case may be, on arm’s length commercial terms. Sales for test marketing, Clinical Trial or Non-Approval Trial purposes or compassionate or similar use shall not be considered to constitute a First Commercial Sale.

1.69 “Force Majeure” shall have the meaning set forth in Article 18.

1.70 “Formulated Bulk VEGF Product” shall mean the VEGF Products formulated into solution, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.

1.71 “FTE” shall mean a full time equivalent employee (i.e. one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [\*\*\*\*\*] hours per year.

1.72 “GAAP” shall mean generally accepted accounting principles in the United States.

1.73 “Global Co-Commercialization Budget” shall mean the annual budget(s) included in a Global Co-Commercialization Plan.

1.74 “Global Co-Commercialization Plan” shall mean the plan, including the related Global Co-Commercialization Budget, prepared by the JCC and approved by the JSC for each VEGF Product covering the Commercialization activities to be performed centrally.

1.75 “Global Marketing Guidelines” shall have the meaning set forth in Section 3.3(a).

1.76 “Good Practices” shall mean compliance with the applicable standards contained in then-current “Good Laboratory Practices,” “Good Manufacturing Practices”

and/or “Good Clinical Practices,” as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.

1.77 “Governmental Authority” shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.78 “ICH” shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.79 “IND” shall mean, with respect to each VEGF Product, an Investigational New Drug Application filed with respect to such VEGF Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.

1.80 “Indemnified Party” shall have the meaning set forth in Section 17.2(a).

1.81 “Indemnifying Party” shall have the meaning set forth in Section 17.2(a).

1.82 “Initial Co-Development Plan” shall have the meaning set forth in Section 5.2.

1.83 “Investor” shall have the meaning set forth in Section 20.16.

1.84 “IPSC” shall have the meaning set forth in Section 3.3(h).

1.85 “Joint Commercialization Committee” or “JCC” shall mean the Joint Commercialization Committee described in Section 3.6(a).

1.86 “Joint Country Commercialization Sub-Committee” shall mean a Joint Country Commercialization Sub-Committee described in Section 3.8(a).

1.87 “Joint Development Committee” or “JDC” shall mean the Joint Development Committee described in Section 3.4(a).

1.88 “Joint Inventions” shall have the meaning set forth in Section 12.1(b).

1.89 “Joint Patent Rights” shall mean Patent Rights that cover a Joint Invention.

1.90 “Joint Steering Committee” or “JSC” shall mean the Joint Steering Committee, as described in Section 3.2(a).

1.91 “Joint Sub-Committees” shall mean, collectively, the Joint Country Commercialization Sub-Committees, the Supply Chain Sub-Committee, the IPSC, the

Finance Sub-Committee, a Joint Technical Transfer Committee and such other subcommittees as the JSC, the JCC or the JDC shall establish.

1.92 “Know-How” shall mean any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings, and other information (whether or not patentable or otherwise protected by trade secret Law) which are now or hereafter during the term of this Agreement owned by, licensed to or otherwise held by a Party or its Affiliates with the rights to license or sublicense the same and that relate to VEGF Trap, a VEGF Product or the Development, Commercialization, manufacture, use, offer for sale or sale thereof.

1.93 “Law” or “Laws” shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority in the Territory.

1.94 “Lead Litigation Party” shall have the meaning set forth in Section 13.1(b).

1.95 “Lead Regulatory Party” shall mean, with respect to each VEGF Product, whichever of (and to the extent) Aventis or Regeneron has been designated hereunder as having responsibility for preparing, prosecuting and maintaining Approvals and Registration Filings relating to such VEGF Product, and for related regulatory duties.

1.96 “Legal Dispute” shall mean any dispute, controversy or claim related to compliance with this Agreement or any Ancillary Agreement (other than the Stock Purchase Agreement) or the validity, breach, termination or interpretation of this Agreement or any Ancillary Agreement (other than the Stock Purchase Agreement).

1.97 “Litigation Party” shall have the meaning set forth in Section 13.1(b).

1.98 “Major Market Country” shall mean any of the following:

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1.99 “Major Market Profit Split” shall mean the Major Market Profit Split, defined and calculated as set forth in Schedule 1.

1.100 “Major Market True-Up” shall have the meaning set forth in Schedule 1.

1.101 “Manufacturing Cost” shall have the meaning and be calculated in accordance with Schedule 1.101.

1.102 “Manufacturing Plan” shall have the meaning set forth in Section 8.7.

1.103 “Marketing Approval” shall mean Approval required for the marketing and sale of a VEGF Product in a country in the Territory.

1.104 “Maximum Regeneron Effort” shall have the meaning set forth in Section 6.9(a).

1.105 “Medical Affairs Cost” shall mean the product of (a) the number of office-based FTEs supporting the coordination of Non-Approval Trials related to VEGF Products as agreed upon in the approved Country Co-Commercialization Plan and Country Co-Commercialization Budget and/or the Global Co-Commercialization Plan and Global Co-Commercialization Budget and (b) the applicable Medical Affairs FTE Rate.

1.106 “Medical Affairs FTE Rate” shall mean on a country-by-country basis (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial based upon the fully burdened cost of medical affairs professionals of major pharmaceutical companies in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the CPI.

1.107 “Modified Clause” shall have the meaning set forth in Section 20.7.

1.108 “Net Sales” shall mean the gross amount invoiced for bona fide arms’ length sales of any VEGF Product by or on behalf of Aventis or its Affiliates or Distributors to Third Parties, less the following deductions, determined in accordance with Aventis’ standard accounting methods as generally and consistently applied by Aventis:

(a) normal and customary trade, cash and/or quantity discounts allowed and taken directly with respect to sales of such VEGF Product;

(b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates and allowances;

(c) chargebacks and other amounts paid on sale or dispensing of VEGF Products;

(d) Third Party cash rebates and chargebacks related to sales of the VEGF Product, to the extent allowed;

(e) retroactive price reductions that are actually allowed or granted;

(f) compulsory payments and rebates directly related to the sale of VEGF Product, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or governmental regulations;

(g) freight, insurance and other transportation charges, to the extent included in the invoice price;

(h) tariffs, duties, excise, sales, value-added, consumption or other taxes (other than taxes based on income), to the extent included in the invoice price; and

(i) any other specifically identifiable costs or charges included in the gross invoiced sales price of such VEGF Product falling within categories substantially equivalent to those listed above.

Sales between the Parties, or between the Parties and their Affiliates or Distributors for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a VEGF Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. In the event that any VEGF Product includes one or more active ingredients other than VEGF Trap, then, prior to the First Commercial Sale of such VEGF Product, the Parties shall agree, through the Finance Sub-Committee, the appropriate method for accounting for sales of such VEGF Product.

1.109 "New Information" shall mean any and all ideas, inventions, data, writings, discoveries, improvements, or materials not generally known to the public, which may arise or be conceived or developed by either Party or jointly during the Term to the extent specifically related to any VEGF Product, including, without limitation, information and data included in the registration dossier.

1.110 "New License" shall mean any license approved in writing by the Parties, other than Existing Licenses, required for the manufacture, Development or Commercialization of any VEGF Product.

1.111 "Non-Approval Trial" shall mean any clinical trial of a VEGF Product other than a Clinical Trial.

1.112 "Offeror" shall have the meaning set forth in Section 20.16(c).

1.113 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by either Party and/or its Affiliates in accordance with the applicable Plan.

1.114 "Overhead Charge" shall mean, beginning in the Contract Year of First Commercial Sale, on a country-by-country basis for each of the Major Market Countries an amount agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in such country to cover [\*\*\*\*\*] such amount to be adjusted as of January 1 of each following calendar year by the percentage increase or decrease, if any, in the CPI. For the avoidance of doubt, "Overhead Charge" shall not include any amounts included in Medical Affairs Cost, Sales Force Cost or any other amounts otherwise included in the definition of "Shared Promotion Expense."

1.115 "Party" or "Parties" shall have the meaning set forth in the introductory paragraph.

1.116 "Party Information" shall mean information or materials provided in connection with this Agreement or any Ancillary Agreement by either Aventis or Regeneron or their respective Affiliates to the other Party or its Affiliates, including, without limitation, by disclosure to any Committee, whether furnished before or after the Effective Date, including, without limitation, information and materials in relation to research, development, manufacturing, promotion, marketing, distributing and selling of VEGF Products hereunder, and information and materials on substances, formulations, techniques, technology, equipment, data, reports, Know-How, sources for supply, patent position, business plans, sales management procedures and other general business and operational processes and procedures. With respect to each Party, Party Information includes New Information other than New Information discovered, invented, authored or otherwise created solely by the other Party.

1.117 "Patent Application" shall mean any application for a Patent.

1.118 "Patent Rights" shall mean unexpired Patents and Patent Applications.

1.119 "Patents" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country.

1.120 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, a corporation, a firm, a trust, an unincorporated organization and a government or other department or agency thereof.

1.121 "Phase IIA Clinical Trial" shall mean a dose exploration, dose response, duration of effect, kinetic/dynamic relationship and/or preliminary efficacy and safety study of a VEGF Product in the target patient population.

1.122 "Phase IIB Clinical Trial" shall mean a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a VEGF Product in the targeted patient population and to define the optimal dosing regimen.

1.123 "Plan" shall mean any Global Co-Commercialization Plan, Country Co-Commercialization Plan, Co-Development Plan, Manufacturing Plan, or other plan approved through the Committee process relating to the manufacture, Development or Commercialization of VEGF Products under this Agreement.

1.124 "Pre-Launch Marketing Expenses" shall mean, with respect to a VEGF Product, on a Therapeutic Area-by-Therapeutic Area basis, all Shared Promotion Expenses incurred beginning [\*\*\*\*\*].

1.125 "Prescription Drug Marketing Act" or "PDMA" shall mean the Prescription Drug Marketing Act of 1987, as amended from time to time.

1.126 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for a VEGF Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the

Territory where governmental authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.127 “Product Trademark” shall mean, with respect to each VEGF Product, the trademark selected by the JCC for use on such VEGF Product and/or accompanying logos, trade dress and/or other indicia of origin, in each case as selected by the JCC; provided, that the trade dress shall be selected by the Joint Country Commercialization Sub-Committee in countries where Regeneron elects to Co-Promote VEGF Products, and in all other countries in the Territory (other than with respect to Product trademarks used by Regeneron in Co-Marketing Countries), by Aventis.

1.128 “Professionals” shall mean physicians and other health care practitioners who are permitted under the Laws of the Co-Commercialization Country in which they work to prescribe the VEGF Products.

1.129 “Promotional Materials” shall mean, with respect to each VEGF Product, promotional, advertising, communication and educational materials relating to such VEGF Product for use in connection with the marketing, promotion and sale of such VEGF Product in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.

1.130 “Publishing Party” shall have the meaning set forth in Section 16.3.

1.131 “Quarterly True-Up” shall mean the Quarterly True-Up, defined and calculated as set forth in Schedule 1.

1.132 “Regeneron” shall have the meaning set forth in the introductory paragraph.

1.133 “Regeneron Commitment Level” shall have the meaning set forth in Section 6.9(a).

1.134 “Regeneron Development Reimbursement Amount” shall have the meaning set forth in Schedule 1.

1.135 “Regeneron Indemnitees” shall have the meaning set forth in Section 17.1(a).

1.136 “Regeneron Intellectual Property” shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.

1.137 “Regeneron Patent Rights” shall mean those Patent Rights now or hereafter during the Term owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement) with the right to sublicense the same and which include at least one claim which would be infringed by the manufacture, use, sale, offer for sale or import of any VEGF Product.

1.138 “Regeneron Sole Inventions” shall have the meaning set forth in Section 12.1(a).

1.139 “Regeneron Trademarks” shall have the meaning set forth in Section 11.3.

1.140 “Regeneron VEGF Products” shall mean the VEGF Trap Products and all other VEGF Products which are now or hereafter during the Term owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement) with the right to license or sublicense the same.

1.141 “Registration Filing” shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any testing, marketing authorization application, supplementary application or variation thereof, IND, BLA, or any equivalent applications in any country.

1.142 “Regulatory Authority” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, marketing, pricing, reimbursement and/or sale of any VEGF Product in a country in the Territory, including, without limitation, the FDA in the United States and EMEA in Europe.

1.143 “Rest of World Countries” shall mean all countries in the Territory that are not Major Market Countries, but excluding any Co-Marketing Country.

1.144 “Rest of World Profit Split” shall mean the Rest of World Profit Split, defined and calculated as set forth on Schedule 1.

1.145 “Rest of World True-Up” shall have the meaning set forth in Schedule 1.

1.146 “Sales Force Cost” shall mean the aggregate of, for each Therapeutic Area, the product of (a) the number of FTEs detailing and Co-Promoting VEGF Products as set forth in the approved Country Co-Commercialization Plan and Country Co-Commercialization Budget and (b) the applicable Sales Force FTE Rate. Notwithstanding the foregoing, neither “Sales Force Cost” nor, for clarity, “Shared Promotion Expenses,” shall include the costs related to any sales representative [\*\*\*\*\*].

1.147 “Sales Force FTE Rate” shall mean on a country-by-country and Therapeutic Area-by-Therapeutic Area basis (a) for each of the Major Market Countries for the Contract Year in which the First Commercial Sale in such country occurs, a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in such country or (b) for each of the Rest of World Countries in which Regeneron has exercised its option to Co-Promote, for the Contract Year in which Co-Promotion begins in such country, a rate agreed upon in local currency by the Parties at the time Regeneron exercises such option, in the case of (a) or (b), based on the fully burdened field force cost of major pharmaceutical companies in such country, such rates to be adjusted as of January 1 of each subsequent calendar year by the percentage increase or decrease, if any, in the CPI.

1.148 "Shared Promotion Expenses" shall mean the sum of the following items, in each case to the extent attributable to Commercialization in the Major Market Countries or which were incurred in accordance with an approved Global Co-Commercialization Plan:

(a) royalties owed to Third Parties on sales in the Major Market Countries, to the extent listed in Part A of Schedule 3 or owed pursuant to agreements executed or amended with the prior written approval of both Parties,

(b) milestones, license fees and all other amounts owed to Third Parties to the extent listed in Part A of Schedule 3 or owed pursuant to agreements executed or amended with the prior written approval of both Parties (in each case, other than any such fees or amounts included in Clinical Supply Cost);

(c) [\*\*\*\*\*];

(d) bad debt attributable to VEGF Products sold in the Major Market Countries;

(e) Sales Force Cost;

(f) Medical Affairs Cost;

(g) Out-of-Pocket Costs in accordance with an approved Global Co-Commercialization Plan or Country Co-Commercialization Plan related to (i) the marketing, advertising and/or promotion of VEGF Products (including, without limitation, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for VEGF Products and (iii) training and communication materials for VEGF Products;

(h) a portion of Out-of-Pocket Costs related to the marketing, advertising and promotion of VEGF Products (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion relates to both VEGF Products and other Aventis products, such portion as agreed upon in an approved Global Co-Commercialization Plan or Country Co-Commercialization Plan;

(i) Out-of-Pocket Costs in accordance with an approved Global Co-Commercialization Plan or Country Co-Commercialization Plan related to Non-Approval Trials for VEGF Products, including without limitation the Out-of-Pocket Cost of CROs, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies and the Out-of-Pocket Cost for purchasing, or Manufacturing Cost to manufacture, as the case may be, comparator agent or placebo requirements;

(j) Manufacturing Cost of VEGF Products, comparator and/or placebo used in Non-Approval Trials in accordance with an approved Global Co-Commercialization Plan or Country Co-Commercialization Plan;

(k) Manufacturing Cost of VEGF Products distributed without charge as part of a compassionate use or patient assistance program;

(l) Overhead Charge;

(m) to the extent not covered by a Party's indemnification obligations under Article 17, amounts paid, whether in damages or by a settlement approved by the Parties, to a Third Party in a Major Market Country as a result of any allegation of (i) infringement by any Party of a Third Party Patent or (ii) product liability, in each case, by, or as a result of, the manufacture, Development or Commercialization of a VEGF Product; and

(n) Out-of-Pocket Costs incurred pursuant to Sections 11.4, 12.2(d), 12.3(b), 13.1(c) or 13.3(c) regardless of whether contained in any approved budget or related to a Major Market Country.

The foregoing shall not include any Out-of-Pocket Costs or other costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will not be unfairly allocated to the VEGF Products (to the extent that any Shared Promotion Expense is attributable, in part, to products or activities other than the VEGF Products).

1.149 "Shares of Then Outstanding Capital Stock" shall mean, at any time, the issued and outstanding shares of Common Stock and Class A Stock of Regeneron at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, or reclassification of Common Stock or Class A Stock distributable, on a pro rata basis, to all holders of Common Stock and Class A Stock.

1.150 "Sole Inventions" shall have the meaning set forth in Section 12.1(a).

1.151 "Stock Purchase Agreement" shall mean the Stock Purchase Agreement, dated as of the Effective Date, between the Parties, which shall constitute an Ancillary Agreement.

1.152 [\*\*\*\*\*].

1.153 [\*\*\*\*\*].

1.154 "Supply Agreement" shall have the meaning set forth in Section 8.1, and shall constitute an Ancillary Agreement.

1.155 "Technical Development Matter" shall have the meaning set forth in Section 10.2.

1.156 "Term" shall have the meaning set forth in Section 19.1(a).

1.157 "Termination Notice Period" shall have the meaning set forth in Section 19.2.

1.158 "Territory" shall mean all the countries of the world, excluding Japan.

1.159 "Therapeutic Area" shall mean each of (i) oncology, (ii) diseases of the eye, or (iii) any other therapeutic grouping of indications for which any VEGF Product may be Commercialized other than oncology and diseases of the eye, such as [\*\*\*\*\*].

1.160 "Third Party" shall mean any Person other than Aventis or Regeneron or any Affiliate of either Party.

1.161 "United States" or "U.S." shall mean the United States of America (including its territories and possessions and its military bases and commissaries wherever located in the Territory) and Puerto Rico.

1.162 "VEGF Products" shall mean [\*\*\*\*\*].

1.163 "VEGF Product Expenses" shall have the meaning set forth in Schedule 1.

1.164 "VEGF Trap" shall mean [\*\*\*\*\*].

1.165 "VEGF Trap Product" shall mean any pharmaceutical products for human and/or animal use which includes VEGF Trap as an active ingredient, alone or in combination with one or more other active ingredients, for any and all indications.

**ARTICLE 2  
COLLABORATION**

2.1 Scope of Collaboration. The Parties agree to cooperate in good faith under this Agreement to Develop and Commercialize VEGF Products in the Territory in such a manner as to optimize the commercial potential of VEGF Products. To achieve these goals, the Parties wish to provide for: (a) the Co-Development of VEGF Products in the Territory; (b) the Co-Promotion of VEGF Products in the Co-Commercialization Countries; (c) the Co-Marketing of VEGF Products in the Co-Marketing Countries; (d) the Commercialization of the VEGF Products in other countries of the Territory; and (e) the manufacture of VEGF Products within the Territory by the Parties as set forth herein. For purposes thereof, the Parties shall establish various Committees as set forth in Article 3 of this Agreement to oversee the Development, manufacture and Commercialization of VEGF Products, and each Party shall, subject to the terms and conditions set forth in Article 16, provide (or cause its Affiliates to provide) to any relevant Committee any necessary confidential Party Information, including, without limitation, New Information, and such other information as may be reasonably required for the Parties to operate effectively and efficiently under this Agreement.

2.2 Compliance With Law. Both Aventis and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in an effort to Develop, manufacture, and Commercialize VEGF Products in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under

or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.

2.3 Commercially Reasonable Efforts. Subject to the terms of this Agreement, each Party (and its Affiliates) shall use Commercially Reasonable Efforts to fulfill all responsibilities assigned to it under this Agreement and any then-applicable Plans.

#### 2.4 Limitation on Exercise of Rights Outside of Collaboration.

(a) During the Term, neither Party nor any of its Affiliates, either alone or through any Third Party shall Develop, manufacture for use in the Territory or Commercialize any VEGF Product in the Territory, except pursuant to this Agreement.

(b) Notwithstanding the foregoing subsection (a), if Regeneron presents a proposal to the JDC to engage in additional Phase IIA Clinical Trials or Phase IIB Clinical Trials to support potential new indications for the VEGF Product and the JDC fails to approve the proposal, then Regeneron may, at its option and at its sole expense, conduct such additional Phase IIA Clinical Trials and Phase IIB Clinical Trials with respect to the VEGF Products outside the scope of the Co-Development Plans; provided, however, Regeneron must first present the proposed protocols and Clinical Trial designs to Aventis for approval, such approval not to be unreasonably withheld or delayed and shall also present to Aventis the related budgets for Clinical Supply Costs and Out-of-Pocket Costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). If, in compliance with this Section 2.4(b), Aventis does not approve any such protocols or Clinical Trial Designs for safety, efficacy or other clinical reasons, Regeneron may not proceed with the proposed Phase IIA Clinical Trials or Phase IIB Clinical Trials unless and until the dispute has been resolved by the Expert Panel in accordance with Section 10.4. In the event that Regeneron conducts any such additional Phase IIA Clinical Trials or Phase IIB Clinical Trials, all results, Know-How and Patent Rights generated in or arising from any such Clinical Trial shall be subject to the grants of rights by Regeneron pursuant to Article 4 of this Agreement. For the avoidance of doubt, no additional consideration shall be payable to Regeneron with respect to the conduct of any such additional Clinical Trials; provided, however, that if the Parties subsequently agree to commence a further Clinical Trial based on the results of such additional Clinical Trial(s), then Aventis shall be required to reimburse Regeneron for the actual Out-of-Pocket Costs and Clinical Supply Costs incurred in connection with the conduct of such additional Clinical Trial(s) and consistent with the budgets provided to Aventis pursuant to this Section 2.4(b) and the other terms of this Agreement. Nothing in this Section 2.4 shall permit Regeneron to make a Registration Filing or seek an Approval in the Territory based on any results or data obtained in conducting the Clinical Trials allowed under this Section 2.4 and publication of all data and results thereof shall be subject to Article 16.

(c) Notwithstanding the foregoing subsection (a), if Aventis determines that an internal product candidate constitutes an Aventis VEGF Product, it shall promptly present a proposal to the JDC to include such Aventis VEGF Product in

the Collaboration on the terms of this Agreement, and, as part of such presentation, shall provide the JDC with all information with respect to such Aventis VEGF Product reasonably available to Aventis and material to a decision by Regeneron's representatives on the JDC as to whether to approve the inclusion of such Aventis VEGF Product in the Collaboration. If Regeneron's representatives on the JDC approve such inclusion of such Aventis VEGF Product in the Collaboration, then such Aventis VEGF Product shall be included in the Collaboration on the terms of this Agreement. If Regeneron's representatives on the JDC do not approve such inclusion of such Aventis VEGF Product in the Collaboration, then Aventis may continue to Develop such Aventis VEGF Product up to the completion of Phase IIA Clinical Trials, at which time Aventis shall present to the JDC the available Clinical Trial data with respect to such Aventis VEGF Product for the approval by Regeneron's representatives on the JDC, which approval shall not be unreasonably withheld or delayed. If Regeneron's representatives on the JDC do not, consistent with this Section 2.4(c), approve the inclusion of such Aventis VEGF Product in the Collaboration on the terms of this Agreement, then Aventis may license or otherwise transfer such Aventis VEGF Product to a Third Party, in which event the Parties shall share equally the net proceeds received by Aventis from such Third Party after recovery by Aventis of its expenditures related to such Aventis VEGF Product.

(d) Notwithstanding the foregoing subsection (a), Aventis may, on a product-by-product basis, initiate an Aventis-sponsored pivotal Clinical Trial in a specific tumor indication which combines an Aventis product with a Third Party VEGF Product, unless: [\*\*\*\*\*]. For any Aventis sponsored pivotal Clinical Trials for a Third Party VEGF Product not prohibited by this subsection (d), Aventis shall notify Regeneron prior to initiating any such trial, such notice to include a brief synopsis of the protocol.

(e) Notwithstanding the foregoing subsection (a), Aventis may initiate an Aventis sponsored pivotal Clinical Trial in [\*\*\*\*\*] so long as Aventis notifies Regeneron in writing of the commencement of such clinical trial, such notice to include a brief synopsis of the protocol.

2.5 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use all Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made in connection with the authorization, execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement, and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions or changes suggested in connection therewith. Each Party will furnish all information required for any applicable

or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.6 [\*\*\*\*\*]

2.7 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Existing Licenses or the New Licenses to which it is a party and to notify the other Party of any terms or conditions in any such Existing License or New License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Moreover, each Party shall take all actions reasonably necessary to ensure such Party's compliance with (a) any such Existing License or New License to which it is a party and any such terms and conditions with which such Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any such material agreement. Neither Party may terminate any Existing License, New License or any other material agreement referred to in clause (b) above with respect to any VEGF Product without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Regeneron is currently negotiating the agreements listed on Part B of Schedule 3 which shall be treated as New Licenses under this Agreement and which shall require the approval of both Parties, such approval by Aventis not to be unreasonably withheld or delayed.

2.8 Plans. The Parties shall undertake all Development and Commercialization activities in accordance with approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.

### **ARTICLE 3 MANAGEMENT**

3.1 Committees/Management.

(a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee, a Joint Development Committee, and a Joint Commercialization Committee. The Parties or such Committees will establish, as sub-committees of the Joint Commercialization Committee, for each Co-Commercialization Country, a Joint Country Commercialization Sub-Committee (each a "Joint Country Commercialization Sub-Committee"). The Parties may agree to establish a Joint Technical Transfer Committee as a sub-committee of the JSC. The roles and responsibilities of each Committee are set forth in this Agreement and may be further designated by the JSC and, in the case of the Joint Country Commercialization Sub-Committee, the Joint Commercialization Committee. Each Party shall bear its own costs associated with its participation in the Committees, and such costs shall not be included in Development Costs or Shared Promotion Expenses.

(b) Each of the Committees and the Executive Officers shall exercise their decision-making authority hereunder in good faith and in a commercially reasonably

manner for the purpose of optimizing the commercial potential of and financial returns from the VEGF Products consistent with other products at a similar stage in development or product life and of similar market potential and without regard to any other pharmaceutical product in Development or being Commercialized or sold by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

### 3.2 The Joint Steering Committee.

(a) Composition. The Joint Steering Committee (the "JSC") shall be established by the Parties to supervise, review and coordinate the performance of the Parties hereunder. The JSC shall be comprised of senior representatives from each of Aventis and Regeneron, selected by such Party. The exact number of representatives of each Party shall be as determined by such Party, but shall include at a minimum the co-chairpersons of the JDC, JCC, Supply Chain Sub-Committee, and Finance Sub-Committee and one additional senior representative from each Party. A Party may change any of its representatives at any time if a new person is appointed to any of the foregoing positions by giving written notice to the other Party. Representatives to the JSC shall be appointed by each Party within thirty (30) days after the Effective Date.

(b) Co-chairpersons of the JSC. The JSC shall have two co-chairpersons, one designated by each of Aventis and Regeneron. The co-chairpersons of the JSC shall be: (i) entitled to set meeting agendas; provided that the agenda shall include any matter reasonably requested by either Party; (ii) required to call emergency meetings of the JSC at the request of a Party; and (iii) required, at the request of either Party, to present JSC disputes that have been unresolved to the Executive Officers. The JSC co-chairpersons shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JSC meetings, which meeting minutes shall be submitted for approval of the members of the JSC.

(c) Meetings of the JSC. The JSC shall meet whenever any member of the JSC shall make such a request in writing to the co-chairpersons (including a request by a Party for an emergency meeting as contemplated by Section 3.2(b)) or whenever a matter is referred to the JSC by any other Committee; provided, however, that the JSC shall in no event meet less frequently than four times per year. Decisions of the JSC shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided that no such vote shall be valid unless each Party is represented by at least one member either by proxy or actual presence at the meeting at which the vote is taken. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member of the JSC to attend meetings where appropriate (e.g., the Alliance Managers, representatives of regulatory affairs or outside consultants). Such additional participants shall not be deemed a member of the JSC, nor shall they have any rights or responsibilities of a member of the JSC.

3.3 Responsibilities of the JSC. The responsibilities of the JSC shall be exercised consistent with this Agreement and shall include, but shall not be limited to, the following:

(a) coordinating the various functional representatives in developing and executing global strategies and plans for the VEGF Products in an effort to ensure global consistency and efficiency, including, but not limited to, establishing global marketing guidelines for determining product pricing, the percentage of sales force incentive compensation linked to VEGF Products and product positioning with regard to VEGF Products (“Global Marketing Guidelines”);

(b) approving target profiles for the VEGF Products;

(c) reviewing and approving on a timely annual basis the Global Co-Commercialization Plan (including the related Global Co-Commercialization Budget), Co-Development Plans (including related Co-Development Budgets) prepared by the JCC and JDC, as the case may be;

(d) reviewing each Country Co-Commercialization Plan (including the related Country Co-Commercialization Budget);

(e) reviewing and approving the Manufacturing Plan and changes thereto as submitted by the Supply Chain Sub-Committee;

(f) reviewing the efforts of the Parties in performing their respective Co-Development, Commercialization and manufacturing activities;

(g) reviewing, and as appropriate requesting, additional information with respect to, the sales performance of the VEGF Products in one or more countries, or throughout the Territory;

(h) establishing as sub-committees of the JSC, a Supply Chain Sub-Committee, Intellectual Property Sub-Committee (“IPSC”), Finance Sub-Committee and such additional Joint Sub-Committees from time to time, each of which: (i) shall be composed of representatives of each Party, with co-chairpersons, and otherwise organized in such a manner as the JSC deems appropriate; (ii) shall be delegated such responsibilities as the JSC deems appropriate; and (iii) shall report to the JSC;

(i) considering and acting upon such other matters as are specified in this Agreement; and

(j) attempting in good faith to resolve any disputes referred to it by any of the other Committee and providing single-point communication for seeking consensus both internally within the respective Party’s organization and together regarding key global strategy and plan issues.

3.4 Joint Development Committee.

(a) Composition. The Joint Development Committee (“JDC”) shall be established by the Parties to, among other things, direct the day-to-day Development work to be conducted under the Co-Development Plans. Unless otherwise agreed by the Parties, the JDC shall be comprised of representatives from each of Aventis and Regeneron, selected by such Party. The exact number of representatives of each Party shall be as determined by such Party, but shall constitute at least two senior representatives from each Party’s research or clinical development organizations, one of whom has responsibility for overseeing oncology programs and the other of whom has responsibility for overseeing ophthalmology programs. Within thirty (30) days after the Effective Date, Aventis and Regeneron will each appoint appropriate representatives to the JDC.

(b) Co-chairperson of the JDC. The JDC shall have two co-chairpersons, one designated by each of Aventis and Regeneron. The co-chairpersons shall be: (i) entitled to set meeting agendas; provided that the agenda shall include any matter reasonably requested by either Party; (ii) required to call emergency meetings of the JDC at the request of a JDC member; and (iii) required, at the request of either Party, to present disputes (together with a JDC member of the other Party) to the JSC pursuant to Section 3.12. The JDC co-chairperson shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JDC meetings, which meeting minutes shall be submitted for approval of the members of the JDC.

(c) Meetings of the JDC. The co-chairpersons of the JDC shall call meetings when deemed by the co-chairpersons to be appropriate or when requested by a Party; provided, however, that such meetings shall be held on a monthly basis for the first year of the Collaboration and on at least a quarterly basis thereafter. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties) or where appropriate, by video or telephone conference. The Parties shall determine the form of the meeting. Decisions of the JDC shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided that no such vote shall be valid unless each Party is represented by at least one member either by proxy or actual presence at the meeting at which the vote is taken. Voting by proxy shall be permissible. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member to attend meetings where appropriate (e.g., representatives of regulatory affairs or outside consultants). Such additional participants shall not be deemed to be members of the JDC, or to have any rights or responsibilities of a member of the JDC.

3.5 JDC Responsibilities The responsibilities of the JDC shall also include, but shall not be limited to:

(a) preparing, or overseeing the preparation of, Co-Development Plans (and related Co-Development Budgets) for final approval by the JSC, and updating each such Plan not less frequently than once per Contract Year;

- (b) monitoring compliance with the Co-Development Plans (including the Co-Development Budgets) and, in connection therewith, reviewing and approving any changes therein;
- (c) approving protocols for Clinical Trials of VEGF Products in the Territory, and monitoring and making modifications to such Clinical Trials;
- (d) reviewing and approving material regulatory correspondence, final study reports, filings and submissions to Regulatory Authorities with respect to VEGF Products, including BLAs;
- (e) [\*\*\*\*\*];
- (f) facilitating an exchange between the Parties of data, information, material and results relating to the Development of VEGF Products in the Territory;
- (g) formulating a life-cycle management strategy for VEGF Products and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;
- (h) preparing procedures for the timely exchange of Adverse Reaction Reports and other information necessary or useful for regulatory filings pursuant to the terms of this Agreement; and
- (i) considering and acting upon such other matters as are specified in this Agreement or by the Joint Steering Committee.

### 3.6 Joint Commercialization Committee.

(a) Composition. The Joint Commercialization Committee (“JCC”) shall be established by the Parties to, among other things, oversee the global Commercialization of the VEGF Products in accordance with the Global Co-Commercialization Plan. Unless otherwise agreed by the Parties, the JCC shall be comprised of representatives from each of Aventis and Regeneron, selected by such Party. The exact number of representatives of each Party shall be as determined by such Party, but shall include at least one senior representative from each Party’s marketing and sales organization(s). Promptly after the Effective Date, Aventis and Regeneron will each appoint representatives to the JCC.

(b) Co-chairpersons of the JCC. The JCC shall have two co-chairpersons, one designated by each of Aventis and Regeneron. The co-chairpersons shall be: (i) entitled to set meeting agendas; provided that the agenda shall include any matter reasonably requested by either Party; (ii) required to call emergency meetings of the JCC at the request of a JCC member; and (iii) required, at the request of either Party, to present disputes (together with a JCC member of the other Party) to the JSC pursuant to Section 3.12. The JCC co-chairpersons shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of the JCC meetings, which meeting minutes shall be submitted for approval of the members of the JCC.

(c) Meetings of the JCC. The co-chairpersons of the JCC shall call meetings when deemed by the co-chairpersons to be appropriate or when requested by a Party; provided, however, that such meetings shall be held on at least a quarterly basis. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the companies) or where appropriate, by video or telephone conference. The Parties shall determine the form of the meeting. Decisions of the JCC shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided that no such vote shall be valid unless each Party is represented by at least one member either by proxy or actual presence at the meeting at which the vote is taken. Voting by proxy shall be permissible. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member to attend meetings where appropriate. Such additional participants shall not be deemed to be a member of the JCC, or to have any rights or responsibilities of a member of the JCC.

3.7 JCC Responsibilities. The responsibilities of the JCC shall also include, but shall not be limited to:

(a) preparing, or overseeing the preparation of, the Global Co-Commercialization Plan (and the related Global Co-Commercialization Budget) for the Commercialization activities to be done centrally, and updating each such Plan not less frequently than once per Contract Year;

(b) preparing the overall global strategy for Commercialization of VEGF Products in the Territory, including, without limitation, VEGF Product branding, positioning, core messages, and other tactical plans as well as the overall pricing strategy;

(c) considering and selecting global Product Trademarks for VEGF Products and giving guidance to the Joint Country Commercialization Sub-Committee on trade dress;

(d) establishing as sub-committees of the JCC the Joint Country Commercialization Sub-Committees;

(e) developing and implementing plans and policies regarding journal and other publications with respect to VEGF Products;

(f) making recommendations to the JSC with respect to target profiles for the VEGF Products; and

(g) considering and acting upon such other matters as are specified in this Agreement or by the JSC.

3.8 Joint Country Commercialization Sub-Committees.

(a) Composition. Each Joint Country Commercialization Sub-Committee will, among other things, oversee the local Commercialization in each Co-Commercialization Country. Unless otherwise agreed by the Parties, each Joint Country

Commercialization Sub-Committee shall be comprised of representatives from each of Aventis and Regeneron, selected by such Party. The exact number of representatives of each Party shall be as determined by such Party.

(b) Co-chairpersons of Each Joint Country Commercialization Sub-Committee. Each Joint Country Commercialization Sub-Committee shall have two co-chairpersons, one designated by each of Aventis and Regeneron. The co-chairpersons shall be: (i) entitled to set meeting agendas, provided that the agenda shall include any matter reasonably requested by either Party; (ii) required to call emergency meetings of each Joint Country Commercialization Sub-Committee at the request of a Joint Country Commercialization Sub-Committee member; and (iii) required, at the request of either Party, to present disputes (together with a Joint Country Commercialization Sub-Committee member of the other Party) to the senior country and/or area management of each Party in the Territory for such Co-Commercialization Country. The co-chairpersons of each Joint Country Commercialization Sub-Committee shall be responsible for recording, preparing and, within a reasonable time, issuing minutes of such Joint Country Commercialization Sub-Committee meetings, which meeting minutes shall be submitted for approval of the members of such Joint Country Commercialization Sub-Committee.

(c) Meetings of Each Joint Country Commercialization Sub-Committee. The co-chairperson of each Joint Country Commercialization Sub-Committee shall call meetings when deemed by the co-chairperson to be appropriate or when requested by a Party; provided, however, that such meetings shall be held on at least a quarterly basis. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the companies, provided, however, that all such meetings shall be held in the applicable local country unless otherwise agreed to by the Joint Country Commercialization Sub-Committee) or where appropriate, by video or telephone conference. The Parties shall determine the form of the meeting. Decisions of each Joint Country Commercialization Sub-Committee shall be made unanimously, each Party having one (1) vote regardless of the number of representatives present or voting; provided that no such vote shall be valid unless each Party is represented by at least one member either by proxy or actual presence at the meeting at which the vote is taken. Voting by proxy shall be permissible. Subject to appropriate confidentiality undertakings where applicable, additional participants may be invited by any member to attend meetings where appropriate. Such additional participants shall not be deemed to be a member of a Joint Country Commercialization Sub-Committee, or to have any rights or responsibilities of a member of a Joint Country Commercialization Sub-Committee.

### 3.9 Joint Country Commercialization Sub-Committee Responsibilities.

(a) The responsibilities of each Joint Country Commercialization Sub-Committee in each Major Market Country shall also include, but shall not be limited to:

(i) preparing, approving and overseeing the preparation of the applicable Country Co-Commercialization Plan (and the related Country Co-Commercialization Budget) for the Commercialization activities to be done in

such Major Market Country, and updating each such plan not less frequently than once per Contract Year

(ii) defining target groups to be covered by overall marketing efforts in the applicable Major Market Country, including, without limitation, key opinion leaders, physician groups, hospitals and regional buying groups, managed care organizations and governmental and government-affiliate buyers;

(iii) establishing the trade dress for each VEGF Product, consistent with the guidelines established by the JCC, in such Major Market Country;

(iv) determining the launch date for each VEGF Product in such Major Market Country, including countries where Pricing Approval is required;

(v) reviewing and approving prices, discounts, rebate, reduction, chargeback and similar policies for such VEGF Product in such Major Market Country, which shall be consistent with the Global Marketing Guidelines;

(vi) preparing short-term and long-term sales forecasts in such Major Market Country;

(vii) working with the Supply Chain Sub-Committee to oversee all recalls, market withdrawals, and any other corrective actions related to any such VEGF Product in such Major Market Country;

(viii) (A) preparing a strategy for Non-Approval Trials, (B) overseeing the design of such trials, and (C) determining which such trials should be conducted, rejected or redesigned and whether any such trials should be referred to the JDC for consideration for inclusion in the Co-Development Plan; and

(ix) considering and acting upon such other matters as are specified in this Agreement or by the JCC.

(b) The responsibilities of each Joint Country Commercialization Sub-Committee in each Rest of World Country shall be limited to, preparing, approving and overseeing the preparation of the applicable Country Co-Commercialization Plan (and the related Country Co-Commercialization Budget) for the sales and marketing activities to be done in such Rest of World Country, and updating each such plan not less frequently than once per Contract Year; provided, however, that the approval by the Joint Country Commercialization Sub-Committee in such Rest of World Country of the Country Co-Commercialization Budget for such Rest of World Country shall be limited to approval of Regeneron's Sales Force Cost and Regeneron's Medical Affairs Cost.

3.10 Rest of World Countries Which Are Not Co-Commercialization Countries. In each Rest of World Country in which a VEGF Product is being Commercialized for which Regeneron has not exercised its right to Co-Commercialize such VEGF Product, Aventis shall, with respect to such VEGF Product, be responsible for:

(a) all decisions with respect to Commercialization activities related to such VEGF Product in such Rest of World Country may be made by, and in the sole discretion of, Aventis, provided such decisions are in accordance with the Global Marketing Guidelines;

(b) informing the JSC of its intent to launch such VEGF Product within six (6) months of the anticipated launch date;

(c) informing the JSC of the First Commercial Sale of such VEGF Product; and

(d) providing the JSC with such information, with regard to the Commercialization activities in such Rest of World Country for such VEGF Product, as the JSC may reasonably request.

3.11 Alliance Management Representative. Each of Aventis and Regeneron shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager (“Alliance Manager”). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among the Committees. Each Alliance Manager will also be responsible for:

(a) coordinating the various functional representatives of Aventis or Regeneron, as appropriate, in developing and executing strategies and Plans for the VEGF Products in an effort to ensure consistency and efficiency;

(b) providing single-point communication for seeking consensus both internally within the respective Party’s organization and together regarding key strategy and Plan issues, as appropriate, including facilitating review of external corporate communications; and

(c) identifying and raising cross-country, cross-Party and/or cross-functional disputes to the JSC in a timely manner.

3.12 Resolution of Governance Matters.

(a) Generally. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible:

(i) in the case of any matter which cannot be resolved by a Joint Country Commercialization Sub-Committee, such matter shall, at the

request of either Party, promptly, and in any event within thirty (30) days after such request, be referred to the senior country or area management of each Party in the Territory for such Co-Commercialization Country for resolution;

(ii) in the case of any matter which cannot be resolved by the JDC or JCC, such matter shall, at the request of either Party, promptly, and in any event within thirty (30) days after such request, be referred to the JSC for resolution; and

(iii) in the event any matter which cannot be resolved by the senior country and/or area management of each Party pursuant to Section 3.12(a)(i) or by the JSC pursuant to Section 3.12(a)(ii), such matter shall, at the request of either Party, be resolved in accordance with the dispute resolution procedures set forth in Sections 3.12(b) and 3.12(c).

(b) Executive Officers' Resolution of Disputes. In the event that the JSC is, after a period of thirty (30) days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, the co-chairpersons of the JSC, by written notice to each Party delivered within five (5) days after receipt of the notice from a Party pursuant to the immediately preceding sentence, shall formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within thirty (30) days of receiving such written notification, failing which, except for Legal Disputes, either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts in accordance with Section 10.4, if such dispute is with respect to a Technical Development Matter.

(c) Interim Budgets Pending Resolution of Disputes. Pending resolution by the Executive Officers of any referred dispute, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the continued Co-Development and Co-Commercialization of the VEGF Products pursuant to this Agreement.

(d) Obligations Of The Parties And Their Affiliates. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder or under an Ancillary Agreement through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement or any Ancillary Agreement which restricts or prohibits a Party from taking any specified action.

**ARTICLE 4**  
**LICENSE GRANTS**

4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement and any license agreement within the Regeneron Patent Rights, Regeneron hereby grants to Aventis and its Affiliates the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to use, manufacture, import, Co-Develop, Co-Commercialize and Co-Market and the exclusive right to import, sell and offer for sale, subject to Regeneron's right to supply VEGF Products to Aventis as contemplated by this Agreement, the VEGF Products during the Term throughout the Territory. For the avoidance of doubt, (i) the foregoing license grant shall not preclude Regeneron from using or otherwise exploiting, or granting any Person the right to use or otherwise exploit, Regeneron Intellectual Property anywhere in the Territory for any purpose other than the manufacture, import, Co-Development, Co-Commercialization, Co-Marketing, offer for sale and sale of VEGF Products for the purposes of the Collaboration throughout the Territory and (ii) the foregoing license grant shall not restrict or prohibit Regeneron's right to manufacture and supply Regeneron VEGF Products for importation into or use or sale in Japan.

4.2 Aventis License Grants. Subject to the terms and conditions of this Agreement and any license agreement within the Aventis Patent Rights, Aventis hereby grants to Regeneron and its Affiliates the nontransferable (except as permitted by Section 20.9), co-exclusive (with Aventis and its Affiliates) right and license under the Aventis Intellectual Property to use, manufacture, import, Co-Develop, Co-Commercialize and Co-Market the VEGF Products during the Term for the purposes of the Collaboration throughout the Territory. For the avoidance of doubt, the foregoing license grant shall not preclude Aventis from using or otherwise exploiting, or granting any Person the right to use or otherwise exploit, Aventis Intellectual Property anywhere in the Territory for any purpose other than the manufacture, import, Co-Development, Co-Commercialization and Co-Marketing of VEGF Products for the purposes of the Collaboration throughout the Territory.

4.3 Sublicenses; Subcontracting. Unless otherwise restricted by any Existing License or New License, the rights granted to either Party and its Affiliates under the Regeneron Intellectual Property or Aventis Intellectual Property, as applicable, are sublicensable with the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however that nothing shall prevent (A) Aventis from sublicensing its rights to a Distributor to sell or offer to sell the VEGF Product in any Rest of World Country and (B) Regeneron from sublicensing its rights to a Distributor to sell or offer to sell the VEGF Product in any Co-Marketing Country that would otherwise have been a Rest of World Country. For the avoidance of doubt, each Party may withhold such consent if it reasonably determines such sublicense would reduce its financial return from the Collaboration in the applicable country. Each Party shall remain responsible and liable for the compliance by its Affiliates and permitted sublicensees and Distributors with applicable terms and obligations set forth herein. Each Party agrees that any sublicense granted pursuant to this Article 4 or Article

11 shall be consistent with, and expressly subject to, the covenants, terms and conditions set forth in this Agreement. Promptly after entering into any such sublicense, or any amendment or modification thereto, the Party granting the license will provide a true and correct copy thereof to the other Party. Each Party shall also have the right to contract with one or more Third Parties to perform certain of its obligations under the Plans if specifically contemplated therein, provided that such Party shall remain responsible and liable for the acts and omissions of such Third Party service providers and such Third Parties undertake in writing obligations of confidentiality and non-use of Party Information which are substantially the same as those undertaken by the Parties under this Agreement. In the event of a breach by a sublicensee or a Third Party contractor of any sublicense or subcontract granted or awarded hereunder by a Party which has or is reasonably likely to have a material adverse effect on the other Party or the other Party's Intellectual Property, then the other Party may cause the Party to exercise, and the Party will promptly exercise, any termination rights it may have under the sublicense or subcontract with such sublicensee or Third Party contractor. All sublicenses and subcontracts granted under this Agreement will terminate upon termination or expiration of this Agreement.

4.4 No Implied License. Except as expressly provided herein, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.

4.5 Technology Transfer. To the extent reasonably necessary for each Party to exercise its rights and perform its obligations under this Agreement with respect to the other Party's intellectual property, and from time to time during the Term, each Party shall provide to the other Party one (1) copy of books and records embodying such Party's applicable intellectual property, to the extent such books and records may exist or be created in the ordinary course of business. Without limiting the generality of any other provision of this Agreement, in accordance with the Co-Development Plan, each Party shall make its scientific and technical personnel reasonably available to the other Party to answer questions or provide instruction as reasonably necessary with respect to such Party's intellectual property, including Know-How, licensed to the other Party hereunder.

## **ARTICLE 5 DEVELOPMENT ACTIVITIES**

5.1 Co-Development of VEGF Products. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to the VEGF Products under the direction and oversight of the Committees and in accordance with all applicable Co-Development Plans. Each Party shall use Commercially Reasonable Efforts to Develop the VEGF Products in the Territory, carry out the Development activities assigned to it in such Co-Development Plans, and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices and export and import control Laws. The Parties intend to conduct Development activities in support of the VEGF Products in the fields of oncology, ophthalmology, and such other

Therapeutic Areas designated by the JDC pursuant to the terms of this Agreement, and, in the Development of VEGF Products, the Parties will use Commercially Reasonable Efforts to differentiate for commercial purposes VEGF Products in different Therapeutic Areas. Except as set forth in Sections 2.4 and 2.6, no Party shall sponsor or initiate any Clinical Trial that has not been approved by the JDC.

5.2 Co-Development Plans. Subject to the terms of Article 3 above, the JDC shall annually prepare Co-Development Plans for VEGF Products for approval by the JSC. Each Co-Development Plan shall incorporate a Co-Development Budget and, except for the initial Co-Development Plan referred to below in this Section 5.2, will be prepared by the JDC to enable JSC approval at least two (2) months prior to the end of the then current Contract Year. Each Co-Development Plan will set forth the plan for Development of each VEGF Product on a calendar-year basis: (a) strategies for Developing and obtaining Approvals for the VEGF Products; and (b) allocation of responsibilities for Development activities between the Parties, and/or to Third Party service providers to the extent permitted by the applicable Co-Development Plan. The activities agreed to by the Parties (together with the associated estimated budget covering the period through December 31, 2004) as set forth on Schedule 5 shall constitute the initial co-development plan (the "Initial Co-Development Plan"). The JDC will meet after the Effective Date to finalize a Co-Development Plan, subject to the review and approval of the JSC, based on the Initial Co-Development Plan. Schedule 5 also sets forth the on-going Clinical Trials for the VEGF Products and the activities that are ongoing and that will need to be completed after the Effective Date as well as the expected budgets for such remaining activities. For the avoidance of doubt, Aventis shall only be responsible for the Development Costs of such on-going Clinical Trials that arise after the Effective Date and Regeneron will remain responsible for all other Development Costs for such on-going Clinical Trials; provided, however such Development Costs relating to such Clinical Trial(s) which are ongoing as of the Effective Date and for which Aventis shall be responsible for paying shall include any cost and expense reasonably allocated to the conduct of such Clinical Trial(s) on or after the Effective Date in accordance with GAAP plus Regeneron's cost of clinical supplies of drugs used after the Effective Date. Estimated Development Costs relating to such ongoing Clinical Trial(s) are included within the Co-Development Budget included within the Initial Co-Development Plan. Unless otherwise agreed to by the JDC, each subsequent Co-Development Plan covering Clinical Trials and other activities included within the Initial Co-Development Plan shall be substantially consistent with the Initial Co-Development Plan and designed to complete as expeditiously as is commercially reasonable such Clinical Trials and other activities described or referred to in the Initial Co-Development Plan. Unless otherwise agreed by the JDC, it is understood that [\*\*\*\*\*]; (b) the JDC will determine the appropriate Party for conducting and overseeing preclinical Development in all Therapeutic Areas; and (c) each of the Parties will have an active involvement in conducting and overseeing clinical Development for each Therapeutic Area for which the other Party has primary responsibility.

5.3 Co-Development Reports. Within forty-five (45) days after the end of each calendar quarter, Regeneron and Aventis shall each provide to the other Party a

written report (in electronic form) summarizing the material activities undertaken by such Party during such quarter in connection with each Co-Development Plan, together with a statement of Development Costs incurred by such Party during such quarter.

## **ARTICLE 6 COMMERCIALIZATION**

6.1 Commercialization of VEGF Products in Co-Marketing Countries In the event (and for so long as) the Parties are not permitted under local Law to Co-Promote a VEGF Product in a country in the Territory, but are permitted to Co-Market such VEGF Product in such country, then Regeneron may elect, prior to First Commercial Sale in such country of such VEGF Product, to Co-Market the VEGF Product in such country in accordance with this Section 6.1 and, to the extent not inconsistent therewith and not prohibited by applicable Law in such country, in accordance with the obligations set forth in this Article 6 and the other provisions of this Agreement. Aventis shall supply Regeneron at Aventis' Manufacturing Cost with its Commercial Supply Requirements of VEGF Products in the Co-Marketing Countries to the extent reasonably available giving higher priority to the Commercial Supply Requirements of countries consistent with their relative contribution to the overall commercial potential of the VEGF Products, and giving equal priority to Aventis' Commercial Supply Requirements in such Co-Marketing Countries. In the event any such provisions of this Agreement are prohibited by applicable Law in a Co-Marketing Country, then such provision shall be considered a Severed Clause under Section 20.7 solely with respect to such Co-Marketing Country.

### 6.2 Co-Commercialization of VEGF Products in Co-Commercialization Countries

(a) Exercise of Option by Regeneron. In the event that Regeneron desires to Co-Promote a VEGF Product in a particular Co-Commercialization Country for use in a Therapeutic Area, Regeneron shall notify Aventis of [\*\*\*\*\*] If Regeneron does not timely notify Aventis of its preliminary indication or of its final decision within the periods set forth in clause (i) or (ii) above, as applicable, Regeneron shall not be entitled to exercise its option to Co-Promote such VEGF Product in such Co-Commercialization Country for use in such Therapeutic Area until on or after the [\*\*\*\*\*].

(b) Co-Commercialization. Aventis and Regeneron (through their respective Affiliates where appropriate) shall Co-Commercialize VEGF Products under the applicable Product Trademarks in each Co-Commercialization Country in accordance with the then-current and applicable Country Co-Commercialization Plan and Country Co-Commercialization Budget. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts to Co-Commercialize the VEGF Products in the Co-Commercialization Countries, carry out the activities assigned to it in the applicable Country Co-Commercialization Plan and conduct all such activities in compliance with applicable Laws. Each Party shall ensure that its Commercialization activities conform with the parameters in the approved Country Co-Commercialization Plan and the Global Co-Commercialization Plan. No Party may initiate or sponsor any Non-Approval Trial in

a Co-Commercialization Country without prior approval from the applicable Joint Country Commercialization Sub-Committee.

(c) Decision to Discontinue Co-Commercialization. In the event that Regeneron decides it no longer wishes to Co-Commercialize a VEGF Product in a particular Co-Commercialization Country for use in a Therapeutic Area or does not wish to maintain its minimum sales force FTE requirement for use in such Therapeutic Area, Regeneron must give Aventis [\*\*\*] prior written notice of such decision. At the end of such [\*\*\*] period, Regeneron shall cease all Co-Commercialization activities with respect to such VEGF Product in such Co-Commercialization Country for use in such Therapeutic Area. Once Regeneron exercises its rights to cease Co-Commercializing in a Co-Commercialization Country for use in a Therapeutic Area, Regeneron will not again be able to exercise its rights pursuant to Section 6.2(a) to Co-Commercialize such VEGF Product in such Co-Commercialization Country, except with the prior written consent of the Joint Country Commercialization Sub-Committee with respect to such Co-Commercialization Country, such consent not to be unreasonably withheld or delayed, it being understood that it shall not be unreasonable for such consent to be withheld if Aventis' representatives on such Joint Country Commercialization Sub-Committee reasonably determine that such Co-Promotion would be inconsistent with the Collaboration Purpose or would require Aventis to unreasonably restructure its sales force. Regeneron shall have the right to recommence Co-Commercialization of a VEGF Product in a Co-Commercialization Country for use in a Therapeutic Area terminated pursuant to this Section 6.2(c) only once. Any such recommencement will occur no earlier than [\*\*\*\*\*] after Regeneron's request therefor.

6.3 Co-Commercialization Plans. The initial Country Co-Commercialization Plan and Country Co-Commercialization Budget for each VEGF Product in each Co-Commercialization Country will be prepared by the applicable Joint Country Commercialization Sub-Committee at least [\*\*\*\*\*] before the Anticipated First Commercial Sale of such VEGF Product in such Co-Commercialization Country. Each Country Co-Commercialization Plan and Country Co-Commercialization Budget for each subsequent Contract Year shall be prepared by the applicable Joint Country Commercialization Sub-Committee at least [\*\*\*\*\*] prior to the end of the then current Contract Year. For the avoidance of doubt any disputes regarding a Country Co-Commercialization Plan or Country Co-Commercialization Budget shall be determined in accordance with Section 3.12. Each Country Co-Commercialization Plan and Country Co-Commercialization Budget shall include, as applicable:

(a) strategies for Co-Promoting the VEGF Products, including recommended target Professionals for such activities, Strengths, Weaknesses, Opportunities and Threats analysis and competitive analysis;

(b) the allocation between the Parties of responsibilities for marketing, sales and promotional activities and, with respect to sales representatives, the percentage of such representatives' time dedicated to the sale of VEGF Products, which shall be

commensurate with the percentage of total annual incentive payments which will be payable to such representatives in respect of their sales of VEGF Products;

(c) anticipated marketing, sales and promotion efforts by each Party (or its Affiliates);

(d) market and sales forecasts in a form to be agreed between the Parties via the applicable Joint Country Commercialization Sub-Committee;

(e) advertising, public relations and other promotional programs and sampling, to be used in the Co-Promotion;

(f) patient advocacy programs, medical affairs programs, including professional symposia and other educational activities, and medical affairs studies based upon Joint Country Commercialization Sub-Committee-approved protocols;

(g) reimbursement and patient assistance, [\*\*\*\*\*];

(h) Non-Approval Trials in the applicable Co-Commercialization Country relating to the VEGF Products, which trials shall be based upon Joint Country Commercialization Sub-Committee-approved protocols; and

(i) as appropriate, a training plan for the Parties' sales representatives.

In addition to the detailed plan and budget for the next upcoming calendar year, each Country Co-Commercialization Plan and Country Co-Commercialization Budget will include an outline of the projected plan and estimated budget for the following calendar year.

#### 6.4 Co-Commercialization Reports.

(a) Within forty-five (45) days after the end of each calendar quarter commencing after the First Commercial Sale (or such earlier agreed upon calendar quarter, as appropriate), Regeneron and Aventis shall each provide to the other Party, in electronic form, a Country Co-Commercialization Report.

(b) Each Party shall, on a periodic and reasonably current basis, keep the applicable Joint Country Commercialization Sub-Committee informed regarding the activities of its sales representatives in promoting the VEGF Products, including information relating to market developments, acceptance of the VEGF Products, product quality complaints, and similar information.

6.5 VEGF Product Pricing and Pricing Approvals. Aventis shall present to the applicable Joint Country Commercialization Sub-Committee for approval proposals for the terms and conditions of sale of each VEGF Product in each Co-Commercialization Country, including proposed pricing, pricing changes, requests for reimbursements, and parameters for any discount or rebate programs. Final decisions concerning VEGF Product conditions of sale, pricing, and discount/rebate programs shall be consistent with

the Global Marketing Guidelines. Aventis will be solely responsible for using Commercially Reasonable Efforts to seek and obtain Pricing Approval in the Co-Commercialization Countries as well as all other countries of the Territory, subject to any pricing parameters established by the JSC. Regeneron shall have the right to participate in any material meetings or the preparation of any material submissions to Governmental Authorities in the Co-Commercialization Countries as well as the United States even if Regeneron has not exercised its right to Co-Promote in the United States.

6.6 Booking of Sales and VEGF Product Distribution. Aventis (or its local Affiliate) shall invoice and book, and appropriately record, all sales of the VEGF Products in the Co-Commercialization Countries as well as all other countries in the Territory (except that Regeneron shall also invoice and book, and appropriately record, its sales of VEGF Products in the Co-Marketing Countries). Aventis (or its local Affiliate) shall also be responsible for the distribution of the VEGF Products and for paying Medicaid and other governmental rebates which are due and owing with respect to the VEGF Products in the Co-Commercialization Countries as well as all other countries in the Territory (except that Regeneron shall be responsible for the VEGF Products sold by Regeneron in the Co-Marketing Countries).

6.7 Field Force Coordination. The applicable Joint Country Commercialization Sub-Committee shall coordinate the Co-Promotion of each VEGF Product by Aventis, Regeneron, their respective local Affiliates and their respective sales representatives in each Co-Commercialization Country. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, and Professional or other customer targeting in order to optimize profits under the Country Co-Commercialization Plan. Without limiting the generality of the foregoing, the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted. [\*\*\*\*\*].

6.8 Contract Sales Force. Each Party shall be entitled to discharge its annual FTE effort with respect to Commercialization of any VEGF Product in any Co-Commercialization Country by engaging a Contract Sales Force to the extent such Contract Sales Force is used [\*\*\*\*\*]. If a Party (or its local Affiliate) retains a Contract Sales Force in a Co-Commercialization Country, that Party (or its local Affiliate) will be responsible for (i) all costs associated with retaining such Contract Sales Force above approved Sales Force Cost included in the applicable Country Co-Commercialization Budget and for the Contract Sales Force's compliance with this Agreement, including, without limitation, the training and monitoring of such Contract Sales Force and ensuring compliance with all applicable Laws, and (ii) ensuring that sales representatives in such Contract Sales Force have minimum skill levels customary for sales representatives in major pharmaceutical companies in such country in the relevant Therapeutic Area.

6.9 Co-Commercialization FTE Efforts.

(a) FTE Efforts. Each Country Co-Commercialization Plan shall specify the FTE effort to be provided by each of the Parties in the applicable Co-Commercialization Country. Upon the exercise of its election to Co-Promote pursuant to Section 6.2(a) in a Co-Commercialization Country, Regeneron will provide to Aventis a binding notice of the FTE effort that Regeneron commits to deliver with respect to such VEGF Product in each Co-Commercialization Country (and in each Therapeutic Area) during the first Contract Year for which Regeneron exercised its right to Co-Promote (the “Regeneron Commitment Level”). Subject to the provisions of Section 6.9(b) and in accordance with Section 6.2(b), in the event that Regeneron elects to Co-Promote in a Co-Commercialization Country in a Therapeutic Area, then (i) in a Major Market Country, in no event shall the Regeneron Commitment Level be less than [\*\*\*\*\*], unless otherwise agreed by the Parties, and (ii) in all other countries the Regeneron Commitment Level shall be as agreed by the Parties. In no event shall the Regeneron Commitment Level exceed fifty percent (50%) of the anticipated total FTE effort in such Co-Commercialization Country for the Therapeutic Area (the “Maximum Regeneron Effort”). [\*\*\*\*\*]. Regeneron’s binding notice referred to above in this Section 6.9(a) shall be accompanied by a plan (which shall be developed by Regeneron in cooperation with Aventis and shall be intended to coordinate and integrate the Parties’ respective FTE efforts and detailing activities) for ensuring that Regeneron will have in place a field force of qualified sales representatives to satisfy the Regeneron Commitment Level. In each Co-Commercialization Country, Aventis shall perform the anticipated total FTE effort above the Regeneron Commitment Level.

(b) Changes in Regeneron Commitment Level. In the event that during the [\*\*\*\*\*], the FTE effort for a VEGF Product is expected to be materially different from the previously anticipated total FTE effort for such VEGF Product, then Regeneron may request that the Parties meet, and in such event the Parties shall promptly meet, to discuss whether to make changes to the Regeneron Commitment Level for such VEGF Product. Regeneron may otherwise change the Regeneron Commitment Level in a Co-Commercialization Country by giving Aventis at least [\*\*\*\*\*] written notice; provided, however, that in no event may the Regeneron Commitment Level exceed the Maximum Regeneron Effort, and provided, further, that any increase in the Regeneron Commitment level shall not be effective if Aventis reasonably determines that such change would have an adverse effect on the Parties’ shared goal of optimizing the commercial potential of the applicable VEGF Product.

(c) FTE Effort and Performance of Details. Each Party’s (or its local Affiliate’s) sales representatives shall provide the FTE effort and detail the VEGF Products in each Co-Commercialization Country in accordance with the approved Country Co-Commercialization Plan. Each Party shall be obligated to deploy the required number of sales representative FTEs for the VEGF Products set forth in the Country Co-Commercialization Plan. [\*\*\*\*\*].

(d) FTE Record Keeping. Each Party (through its local Affiliates where appropriate) shall maintain records relating to its sales representative FTEs for the VEGF Products in the Co-Commercialization Countries in a manner sufficient to permit

the determination of the Sales Force Cost and the incentive compensation requirements set forth in Section 6.9(c) above in each Co-Commercialization Country.

#### 6.10 Training.

(a) Each Party (through its local Affiliates where appropriate) shall, at its own expense, comply with the training plan contained in any Country Co-Commercialization Plan.

(b) Prior to the First Commercial Sale in any Co-Commercialization Country, the Parties (through their local Affiliates where appropriate) shall jointly develop sales training materials for use in training each Party's sales representatives with respect to their activities in such Co-Commercialization Country. The Parties (through their local Affiliates where appropriate) will thereafter cause their training personnel to train their field sales representatives with such training materials and Promotional Materials with respect to their activities in such Co-Commercialization Country.

(c) If either Party (including through any of its respective local Affiliates) organizes material VEGF Product-related meetings of its employees (such as launch meetings) for a particular Co-Commercialization Country, it will make Commercially Reasonable Efforts to give the other Party (or its local Affiliate) advance notice of any such meetings. If requested by the other Party (or its local Affiliate), the Party (or its local Affiliate) organizing such meetings will permit representatives of the other Party (or its local Affiliate) to attend and participate in such meetings or such portions thereof which relate solely to the Co-Commercialization of the VEGF Products at their own cost. In such event and to the extent possible, the Party organizing such meeting shall keep the VEGF Product-related portions of such meetings independent from other matters.

(d) In a manner determined by the applicable Joint Country Commercialization Sub-Committee, the Parties (through their local Affiliates where appropriate) will coordinate the detailing, sales meetings, contacts with wholesalers and retailers, targeting of healthcare organizations, speaker programs and, as appropriate, medical affairs and/or support activities for relevant Non-Approval Trials as provided in the relevant Country Co-Commercialization Plan.

6.11 Promotional Materials. In the Co-Commercialization Countries, the Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the VEGF Products which, in each case, are provided for in the relevant Country Co-Commercialization Plan and are approved by the applicable Joint Country Commercialization Sub-Committee. In each Co-Commercialization Country, the applicable Joint Country Co-Commercialization Sub-Committee will prepare Promotional Materials for the VEGF Products which are intended for use within such Co-Commercialization Country. Aventis will have primary responsibility, with Regeneron's participation, for the preparation of Promotional Materials intended for use in a Co-Commercialization Country. Each Party shall send to its regulatory compliance personnel samples of the Promotional Materials and such

regulatory personnel shall review and either approve or state their reasons for disapproval of such Promotional Materials in writing within ten (10) Business Days following its receipt of such sample. Aventis shall be responsible for the distribution of Promotional Materials for use in the Co-Commercialization Country and shall ensure that Regeneron's sales representatives are provided with reasonable quantities of Promotional Materials consistent with the Regeneron Commitment Level for such Co-Commercialization Country in accordance with the approved Country Co-Commercialization Plan. The Parties shall jointly own all rights to all Promotional Materials, including all copyrights thereto. All Promotional Materials generated for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved as set forth in this Section. In all countries other than the Co-Marketing Countries, Aventis shall be responsible for preparing all Promotional Materials for the VEGF Products which are intended for use within such countries, which shall, to the extent that such materials relate to the VEGF Products in the case of multiple product materials, be approved by the Joint Country Commercialization Sub-Committee; provided, however, if Regeneron has not exercised its right to Co-Promote in a Major Market Country, the JCC shall approve the Promotional Materials intended for use in that Major Market Country. At the request of the JSC, Aventis Affiliates in the Rest of World Countries shall send representative samplings of Promotional Materials used in such countries to the JSC for review.

6.12 Promotional Claims/Compliance. Neither Party (nor any of its respective Affiliates) shall make any medical or promotional claims for any VEGF Product other than as permitted by applicable Laws. When distributing information related to any VEGF Product or its use (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party (and its respective Affiliates) shall comply with all applicable Laws (and, with respect to the U.S., in accordance with the Pharmaceutical Research Manufacturers of America Code on Interactions with Healthcare Professionals).

6.13 Samples. Aventis shall provide Regeneron with VEGF Product samples as required in the applicable Country Co-Commercialization Plan and as decided by the Joint Country Commercialization Sub-Committee. Aventis and Regeneron (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable, approved Country Co-Commercialization Plan and shall store and distribute samples in full compliance with applicable Laws, including the requirements of the PDMA. Each Party (and its local Affiliates) will maintain those records required by the PDMA and all other Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the VEGF Product samples on request.

6.14 [\*\*\*\*\*]

6.15 Inventory Management. Aventis, with respect to each Co-Commercialization Country, shall use Commercially Reasonable Efforts to manage VEGF Product inventory on hand at wholesalers and other Distributors so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.

6.16 Medical and Consumer Inquiries. The applicable Joint Country Commercialization Sub-Committee or the JCC in the United States if Regeneron has not exercised its right to Co-Promote in the United States shall delegate responsibility for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding VEGF Products in the applicable country. In the Co-Commercialization Countries and the United States, if not a Co-Commercialization Country, each Party shall refer all such questions about VEGF Products that it receives to the Party or Parties responsible for responding thereto as set forth herein, and each Party shall inform the other Party of any answers given, all in accordance with the laws, regulations and policies of the FDA. In the Co-Commercialization Countries and the United States, if not a Co-Commercialization Country, the Parties shall work together to formulate, and shall mutually agree upon, responses to such inquiries, including the content of any Frequently Asked Questions (FAQs). If appropriate, the Parties shall establish a centralized database to document and track medical inquiries. If Regeneron receives any questions about VEGF Products in a country other than the Co-Commercialization Countries or the United States, if not a Co-Commercialization Country, Regeneron shall refer all such questions to Aventis and Aventis shall be responsible for responding thereto.

6.17 Market Exclusivity Extensions. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to market, price and sell a VEGF Product in such country, and (b) no generic equivalent of a VEGF Product is marketed in such country.

6.18 Non-Compete. During the Term, except as expressly permitted by Section 2.4, neither Aventis nor Regeneron (nor their respective Affiliates or sublicensees under this Agreement) shall, directly or indirectly, either alone or through any Third Parties, Develop, manufacture for use or sale in any part of the Territory, or Commercialize any VEGF Products in the Territory except for VEGF Products Developed, manufactured or Commercialized pursuant to this Agreement. In the event that (i) Regeneron terminates this Agreement for any reason or (ii) Aventis terminates this Agreement for any reason other than pursuant to Section 19.3 or Section 19.4, [\*\*\*\*\*], Aventis (nor its respective Affiliates or sublicensees under this Agreement) shall not, directly or indirectly, Commercialize any VEGF Products in any part of the Territory. In the event that Aventis terminates this Agreement pursuant to Section 19.3 or Section 19.4, [\*\*\*\*\*], Regeneron (nor its respective Affiliates or sublicensees under this Agreement) shall not, directly or indirectly, Commercialize any VEGF Products in any part of the Territory other than VEGF Products as to which, as of the effective date of such termination, Regeneron continues to have ownership of, and/or pursuant to Schedule 8, has a post-termination license right. A Party shall not be considered in breach of this Section 6.18 solely by reason of the acquisition by such Party of a Person (a) if such Party includes the offending VEGF Product(s) in the licenses granted to the other Party pursuant to this Agreement or (b) prior to the closing of such acquisition, the acquiring Party commits in writing to the other Party that, promptly following the closing of such

acquisition, it will divest itself of the offending rights and/or activity, and the acquiring Party uses Commercially Reasonable Efforts to pursue such divestiture, and in the event that such divestiture is not completed within six (6) months of the closing of such acquisition, the acquiring Party ceases all Development, manufacturing and/or Commercialization, as applicable, of the offending VEGF Product(s) or includes the offending VEGF Products(s) in the licenses granted to the other Party pursuant to this Agreement.

6.19 Post Marketing Clinical Trials. Subject to the provision of this Agreement, the Parties shall use Commercially Reasonable Efforts to comply with any Clinical Trial obligations with respect to registration Approval with respect to any VEGF Product in any country in the Territory, imposed by applicable Law, pursuant to the approvals or required by a Regulatory Authority.

**ARTICLE 7  
CLINICAL AND REGULATORY AFFAIRS**

7.1 Ownership of Approvals and Registration Filings.

(a) Regeneron shall own all Approvals and Registration Filings, with respect to the VEGF Products in the United States and shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto. [\*\*\*\*\*].

(b) [\*\*\*\*\*].

(c) Regeneron in the United States and Aventis in all countries outside of the United States in the Territory shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the VEGF Product in the jurisdiction as to which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article 7. The Lead Regulatory Party shall perform all such activities in accordance with the Co-Development Plans, Global Co-Commercialization Plans, applicable Country Co-Commercialization Plans, and all applicable Laws.

(b) The Parties shall establish procedures to ensure that the Parties exchange on a timely basis all necessary information to enable the Lead Regulatory Party to comply with all regulatory obligations on a global basis, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements, and investigator notifications to Regulatory Authorities. The Parties shall provide to each other prompt written notice of any Approval of a VEGF

Product. Whenever possible, the Lead Regulatory Party shall give the other Party adequate time to review and comment on all material submissions to Regulatory Authorities relating to a VEGF Product, including, without limitation, those related to Pricing Approvals. The Parties will meet to discuss in good faith any disputes on the contents of filings or submissions to Regulatory Authorities and such disputes shall be submitted to the JDC for timely resolution.

(c) The Parties shall work together cooperatively (i) in the preparation of proposed product labeling and any negotiations with Regulatory Authorities regarding VEGF Product labeling, (ii) in the preparation of regulatory strategies with respect to all regulatory actions, communications, filings and submissions, including any supplements and amendments to Registration Filings, (iii) to prepare for advisory committee or any other regulatory meeting concerning VEGF Products, and (iv) in the response to Regulatory Authorities to any of the communications or inquiries referred to in Section 7.5(b)(i)-(vi). Such cooperation shall include providing the other Party with prompt written notice of material pending submissions and/or meetings with Regulatory Authorities and an opportunity to actively participate in the drafting of material submissions and active participation in meetings and telephone conferences. These regulatory matters shall be conducted with the guidance of the JDC (and the Joint Country Commercialization Sub-Committee, if applicable). The JDC shall oversee the implementation of a plan for the global registration and regulatory strategy for Registration Filings in the Territory, including the schedule for such filings and submissions. All material regulatory decisions for the VEGF Products shall be made through the JDC.

(d) Without limiting anything in this Section 7.2, in the United States, the Lead Regulatory Party for the applicable IND or BLA, as the case may be, shall use all reasonable efforts to provide the other Party with reasonable advance written notice of any filings, submissions, meetings, telephone conferences and/or other discussions by or of such Lead Regulatory Party with the FDA, scheduled or unscheduled, that pertain to the applicable VEGF Product, and, consistent with applicable Laws, and shall use all reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such filings and submissions, and to attend and actively participate in all such meetings, telephone conferences and/or discussions with the FDA, and shall provide the other Party with copies of all such filings and submissions of and of any minutes of any such meetings, telephone conferences and/or discussions. In addition, the Lead Regulatory Party for the applicable IND or BLA, as the case may be, shall use all reasonable efforts to provide the other Party with all information, data and materials reasonably necessary for the other Party to participate in such activities, said items to be provided to the other Party, where possible, at least seven (7) days in advance of the date on which the applicable activity is expected to occur. The Parties will meet to discuss in good faith any disputes on the contents of filings or submissions to the FDA and disputes shall be submitted to the JDC for timely resolution.

(e) [\*\*\*\*\*].

7.3 Regulatory Meetings Outside the United States. Aventis shall be responsible for interfacing, corresponding and meeting with the applicable Regulatory Authorities and Governmental Authorities with respect to each VEGF Product in the Territory outside the United States. Regeneron shall have the right to have representatives participate in all material meetings and telephone discussions between representatives of Aventis and applicable Regulatory Authorities in the Territory outside the United States with respect to each VEGF Product.

7.4 Regulatory Communications and Correspondence. The Lead Regulatory Party shall, within two (2) Business Days, provide to the other Party copies of any material correspondence received from or submitted to the applicable Regulatory Authorities pertaining to each VEGF Product (including, without limitation, any meeting minutes). To the extent a Party is not the Lead Regulatory Party with respect to a VEGF Product, such Party shall use all reasonable efforts to ensure that, except in extraordinary circumstances, such Party will not communicate or correspond with, and will use all reasonable efforts to facilitate the Lead Regulatory Party as the sole party corresponding or communicating with, any Regulatory Authority concerning a VEGF Product; provided, however, that nothing herein shall limit or restrict the right of the Party which is not such Lead Regulatory Party to communicate with any Regulatory Authority in connection with its manufacturing facilities or other operations, unless such communications relate directly to the manufacture, Development, or Commercialization of such VEGF Product. In furtherance of this, the Party which is not the Lead Regulatory Party will take reasonable steps and implement reasonable procedures intended to assure the foregoing.

#### 7.5 Assistance.

(a) Each Party shall cooperate with the other Party to provide all necessary information and reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party (i) to comply with any Law applicable to any VEGF Product in the Territory, and (ii) to submit, obtain, maintain and update Approvals with respect to each VEGF Product in the Territory.

(b) Such assistance and actions shall include, among other things, keeping the other Party informed, commencing within forty-eight (48) hours after notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party, or other Governmental Authority, which (A) raises any material concerns regarding the safety or efficacy of any VEGF Product, (B) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with any VEGF Product, or (C) is reasonably likely to lead to a recall or market withdrawal of any VEGF Product. Information that shall be disclosed pursuant to this Section 7.5(b) shall include, but not be limited to:

- (i) governmental or regulatory inspections of manufacturing, distribution or other related facilities used for any VEGF Product;

(ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities relating to any VEGF Product;

(iii) any communication from Regulatory Authorities or other Governmental Authorities pertaining to the testing, manufacture, sale, pricing, reimbursement, promotion or distribution of any VEGF Product and any other Regulatory Authority or other Governmental Authority reviews or inquiries relating to any VEGF Product;

(iv) receipt of a warning letter relating to any VEGF Product;

(v) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction concerning any VEGF Product; and

(vi) receipt of product complaints concerning actual or suspected product tampering, contamination, or mix-up (e.g., wrong ingredients).

#### 7.6 Pharmacovigilance and Safety Data Exchange.

(a) Both Parties will cooperate with each other in order to fulfill all the safety, efficacy and regulatory requirements in all countries of the Territory in which the VEGF Products are being tested, marketed, distributed, or developed.

(b) Without limitation to the foregoing, the Parties shall follow specific procedures to be agreed upon which shall coordinate the exchange of necessary safety information to ensure prompt communication of such notifications and compliance with the reporting obligations to all the respective Regulatory Authorities as well as in handling product complaints. Both Parties will agree to implement a separate agreement, which explains the pharmacovigilance responsibilities and establishes procedures for safety information exchange. This pharmacovigilance agreement is to be completed within ninety (90) days after the Effective Date.

7.7 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a VEGF Product, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will immediately provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses that concern a VEGF Product, provided that the other Party shall have the right to review and comment on such responses, and such other Party shall consider in good faith the comments made by such Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the

response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within twenty-four (24) hours of receipt of notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities being used or proposed to be used for the manufacture of VEGF Products.

7.8 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any VEGF Product in the Territory shall be made only upon mutual agreement of the Parties; provided, however, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or applicable Law. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal.

7.9 Cost of Recalls and Other Corrective Actions. Except as otherwise provided in this Section 7.9, the Parties will share all costs of a recall, market withdrawal or other corrective action with respect to any VEGF Product in the Territory as a Shared Promotion Expense. Notwithstanding the foregoing, a Party shall bear any and all costs of a recall, market withdrawal or other corrective action with respect to a VEGF Product in the Territory, including the COGS for the VEGF Product in question, to the extent the recall, market withdrawal, or other corrective action is attributable predominantly to the fault of such Party and results from (a) a negligent or reckless act or omission or intentional misconduct of such Party (or its Affiliate, agent or sublicensee), (b) the failure of the Party responsible for manufacturing the VEGF Product to perform its responsibilities and manufacture the VEGF Product in compliance with specifications or with applicable Laws, including applicable Good Manufacturing Practices, or (c) a breach of any Laws or the terms of this Agreement.

## **ARTICLE 8 MANUFACTURING AND SUPPLY**

8.1 Supply Agreement. Within ninety (90) days after the Effective Date, the Parties shall enter into one or more supply agreements (each a "Supply Agreement"), containing customary terms and conditions with respect to the forecasting, ordering and delivery of Finished VEGF Products and/or Formulated Bulk VEGF Products and shall specify that the price for Finished VEGF Products and Formulated Bulk VEGF Products shall be the Manufacturing Cost. Each Supply Agreement shall include as an annex thereto, a customary quality agreement containing terms and conditions regarding quality assurance and Good Practices with respect to the manufacture of VEGF Trap Products or Formulated Bulk VEGF Products.

8.2 Manufacture and Supply of Clinical Supply Requirements of VEGF Trap. Regeneron shall use Commercially Reasonable Efforts to use its Existing Facility in accordance with the Manufacturing Plan to provide an adequate and timely supply of Clinical Supply Requirements of Finished VEGF Trap Product or Formulated Bulk VEGF Product until the earlier of (a) the date of the First Commercial Sale of the first VEGF Trap Product, or (b) the date that Aventis is capable of producing such Clinical Supply Requirements on its own or through a Third Party manufacturer. Regeneron shall

supply such Clinical Supply Requirements of the VEGF Trap Product at Regeneron's Clinical Supply Cost; provided that if such Clinical Supply Requirements are for a VEGF Trap Product that is also manufactured by Regeneron for Commercial Supply Requirements, such Clinical Supply Requirements shall be supplied at the Manufacturing Cost set forth in Schedule 1.98 for Commercial Supply Requirements.

8.3 Aventis Manufacturing and Supply Obligations. Aventis shall use Commercially Reasonable Efforts to provide an adequate and timely supply of Commercial Supply Requirements and, except as set forth in Section 8.2, Clinical Supply Requirements of VEGF Products in the Territory for the Collaboration. Aventis shall supply Clinical Supply Requirements and Commercial Supply Requirements for the Collaboration at Aventis' Manufacturing Cost for each VEGF Product. Aventis may satisfy its requirements under this Section 8.3 through one of its existing manufacturing facilities, by, at its own expense, constructing and obtaining all required approvals and validations by Regulatory Authorities for, a new manufacturing facility, or, with Regeneron's prior consent (and consistent with the Collaboration Purpose), either (i) by paying for the expansion and scale-up of Regeneron's Existing Facility as contemplated by the Manufacturing Plan or (ii) through a Third Party manufacturer; provided that, in each case, such activities are consistent with the Manufacturing Plan prepared by the Supply Chain Sub-Committee (with input from the JDC) and approved by the JSC pursuant to Section 8.7. All costs and expenses (including capital expenditures) required to provide additional manufacturing capacity (including, if applicable, at the Existing Facility), including without limitation the related start-up and validation activities contemplated by the Manufacturing Plan, shall be paid by Aventis, it being understood and agreed that upon its purchase thereof as contemplated by the Manufacturing Plan, [\*\*\*\*\*].

8.4 Manufacturing Compliance. Each Party shall be responsible for manufacturing VEGF Products in accordance with all applicable Laws, including applicable Good Manufacturing Practices. The Parties will enter into a separate quality agreements containing terms and provisions customary for that type of agreement in the pharmaceutical industry. One of the quality agreements may constitute an annex to the Supply Agreement. Both Parties shall use Commercially Reasonable Efforts to minimize Manufacturing Cost for each VEGF Product.

8.5 Manufacturing Shortfall. Each Party shall be required to provide prompt written notice to the other Party if it reasonably determines that it will not be able to supply the agreed upon demand forecast for the VEGF Products. Upon such notification, the matter shall be referred to the Supply Chain Sub-Committee (or the JSC) to determine what, if any alternative supply source of VEGF Product (an "Alternative Supplier") should be identified and established. The goal of the Parties in identifying an Alternative Supplier will be first to use the internal capacity of Aventis and/or its Affiliates and/or Regeneron to fill the supply shortfall, such that the manufacturing Party shall be considered the Alternative Supplier for purposes of this Section 8.5. In the event the Supply Chain Sub-Committee (or JSC) agrees to establish an Alternative Supplier, each Party shall transfer or license (on a royalty free basis) Know-How and Patent Rights necessary to transfer production to such Alternative Supplier in a timely manner and

provide reasonable assistance to the Alternative Supplier to effect such transfer. Any increase in COGS and any other reasonable and direct costs directly associated with the transfer of production responsibilities to Alternative Suppliers shall be borne exclusively by the Party responsible for the shortfall. For purposes of the preceding sentence, a Party shall not be deemed responsible for such shortfall to the extent such shortfall arises from a material increase in Commercial Supply Requirements from that in the agreed upon demand forecast that could not reasonably be anticipated and supplied through the exercise of Commercially Reasonable Efforts.

8.6 Distribution. Aventis (or its local Affiliate) shall be responsible for the distribution of the VEGF Products in countries other than the Co-Marketing Countries. Each Party will be responsible for its own distribution of VEGF Products in the Co-Marketing Countries. Aventis will maintain and manage VEGF Product inventory levels based on a JCC approved risk assessment and inventory management policy.

8.7 Manufacturing Plans. The Parties, through the Supply Chain Sub-Committee, will agree upon the VEGF Product manufacturing plan (the "Manufacturing Plan") providing for Regeneron's manufacture and supply of Clinical Supply Requirements in accordance with Section 8.2 and Aventis' manufacture and supply in accordance with Section 8.3. In addition, the Manufacturing Plan shall reflect the Parties' intention to use Commercially Reasonable Efforts to minimize Manufacturing Cost for each VEGF Product. The Supply Chain Sub-Committee will prepare and update the Manufacturing Plan coordinating the entire supply chain to support all VEGF Product needs and coordinate with the Joint Development Committee to prepare associated regulatory strategy and procedures. The initial Manufacturing Plan is annexed hereto as Schedule 7. The Parties shall use Commercially Reasonable Efforts to perform their responsibilities in accordance with the Manufacturing Plans. The Manufacturing Plan shall include plans for appropriate back-up manufacturing facilities and inventory levels typically maintained to prevent any interruption, discontinuity or other impediment to continued supply of VEGF Products.

8.8 Co-Marketing Supply. In the event of a Co-Marketing of any VEGF Product, the Parties will negotiate in good faith a separate Supply Agreement providing for the supply of such VEGF Product at the agreed upon price and containing terms and provisions customary for that type of agreement in the pharmaceutical industry as deemed necessary and/or required and/or advisable by the Parties. Any such supply agreement shall be considered an Ancillary Agreement.

8.9 Manufacturing Changes. Any changes of the manufacturing or quality testing process or the related sites, for the Finished VEGF Products or Formulated Bulk VEGF Product, which may have an influence on (i) the quality of the VEGF Products or on (ii) the regulatory status of the VEGF Products, other than those required by applicable Law, shall require the prior written approval of the Parties.

**ARTICLE 9**  
**PERIODIC REPORTS; PAYMENTS**

9.1 Sharing of Collaboration Profits and Losses.

(a) Recognizing the joint nature of the Collaboration, and the degree of risk and opportunity contemplated by each of the Parties hereunder, commencing on the Effective Date and continuing during the Term, the Parties shall share (i) the Major Market Profit Split in the Major Market Countries (other than any Co-Marketing Country), and (ii) the Rest of World Profit Split in the Rest of World Countries, in each case, as described in Schedule 1.

(b) Commencing on the Effective Date and continuing during the Term, Aventis shall be responsible for paying one hundred percent (100%) of the total Development Costs incurred in accordance with the terms of this Agreement and the applicable Co-Development Budget, by or on behalf of Aventis, Regeneron, and their respective Affiliates, subject to Aventis' right to receive Development Payments (as defined in and calculated in accordance with Schedule 1) during the Term. Regeneron shall be responsible for any development costs incurred prior to the Effective Date, unless they qualify to be treated as Development Costs pursuant to Section 5.2.

9.2 Periodic Reports. Aventis and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below in this Section 9.2:

(a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Sections 5.3 and 6.4;

(b) Within twenty (20) days following the end of each month, Aventis shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each VEGF Product by country in Euro or such other currency as used by Aventis in its internal reporting systems;

(c) Within forty-five (45) days following the end of each calendar quarter, Aventis shall deliver electronically to Regeneron a written report setting forth, on a country-by-country basis for such quarter: (i) the Net Sales of each VEGF Product in local currency and, in Euro, (ii) in Major Market Countries, and any Rest of World Countries where readily available, quantities sold by dosage form and unit size, (iii) with respect to the United States, an accounting of the deductions from gross sales permitted by the definition of Net Sales, and (iv) in Major Market Countries, gross sales of VEGF Products;

(d) Within forty-five (45) days following the end of each calendar quarter, each Party shall deliver electronically to the other Party a written report setting forth in reasonable detail the Development Costs incurred by such Party in such calendar quarter;

(e) Within forty-five (45) days following the end of each calendar quarter, each Party that has incurred any Shared Promotion Expense in accordance with

an approved Global Co-Commercialization Plan and/or an approved Country Co-Commercialization Plan in that calendar quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Shared Promotion Expense incurred by such Party in such calendar quarter;

(f) Within forty-five (45) days following the end of each calendar quarter, Regeneron shall deliver electronically to Aventis a written report setting forth on a country-by-country basis Regeneron's Sales Force Cost and Regeneron's Medical Affairs Cost in each Rest of World Country as set forth in the approved Country Co-Commercialization Plan and Country Co-Commercialization Budget for such country for such calendar quarter; and

(g) Within sixty (60) days following the end of each calendar quarter, Aventis shall deliver electronically to Regeneron a Consolidated Net Profit/Loss Report in respect of such calendar quarter, combining the information reported by each Party and showing its calculations in accordance with Schedule 1 of the amount of any payments to be made by the Parties hereunder for such quarterly period as contemplated by Section 9.3 and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.2 shall be in such form, format and level of detail as may be approved by the Joint Finance Sub-Committee.

9.3 Funds Flow. If Aventis is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Net Profit/Loss Report, it shall make such payment to Regeneron within ten (10) days after its delivery to Regeneron of such Consolidated Net Profit/Loss Report. If Regeneron is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Net Profit/Loss Report, it shall make such payment to Aventis within ten (10) days after its receipt of such Consolidated Net Profit/Loss Report from Aventis. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each calendar quarter, Aventis shall pay Regeneron the amount of royalties payable under any Existing License or New License to which Regeneron is a party on account of VEGF Product sales in the Territory.

#### 9.4 Upfront Payments and Milestone Payments.

(a) In partial consideration for the funding of development of the VEGF Products, Aventis shall pay to Regeneron a non-refundable, non-creditable upfront payment of U.S. \$80,000,000 (which shall not be reduced by any withholding or similar taxes), within three (3) Business Days of the Effective Date.

(b) In addition to the other payments contemplated herein, Aventis shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 2 to Regeneron upon the occurrence of the applicable milestone event. Aventis shall have five (5) Business Days after the achievement of any such milestone to pay the corresponding amount to Regeneron, in each case, which shall not be reduced by any withholding or similar taxes.

9.5 Revenue and Expenses in Co-Marketing Countries. Subject to the terms of the final sentence of Section 6.1, each Party shall retain all revenues accrued by such Party (or its relevant local Affiliate) on its sales of any VEGF Product in each Co-Marketing Country. Each Party shall be responsible for its own costs and expenses incurred with respect to any VEGF Product in each Co-Marketing Country. Within thirty (30) days following the end of each calendar quarter following the First Commercial Sale in any Co-Marketing Country, each Party shall provide the JCC with a detailed report of Net Sales made by the Party or its local Affiliates in Co-Marketing Countries. The format and timing of such reports shall be as approved by the Joint Finance Sub-Committee.

9.6 Invoices and Documentation. The Joint Finance Sub-Committee shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder and thereunder.

9.7 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to U.S. Dollars using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of that month.

9.8 Late Payments. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (National Edition) effective for the date on which the payment was due, [\*\*\*\*\*](such sum being referred to as the "Default Interest Rate").

9.9 Taxes. Except as set forth in Section 9.4, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder or the Ancillary Agreements, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall furnish the other Party with proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

9.10 Adjustments to FTE Rates/Overhead Charge. Notwithstanding anything herein to the contrary, upon the request of either Party (such request to occur not more than once every three years for any Major Market Country), the Parties shall meet to review the accuracy of an applicable FTE rate used herein in any Major Market Country (e.g., Sales Force FTE Rate, Medical Affairs FTE Rate, Development FTE Rate, etc.) or Overhead Charge. The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate(s) and Overhead Charge and to determine in good faith whether to adjust the rates or charges in such Major Market Countries.

## **ARTICLE 10 DISPUTE RESOLUTION**

10.1 Resolution of Disputes. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.

10.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article 3 shall be resolved pursuant to Article 3 and, to the extent such matters constitute a Technical Development Matter, Section 10.4, except in each case to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For purposes of this Agreement, the term "Technical Development Matter" shall mean (i) any matter with respect to the Development of a VEGF Product involving the determination of any trial design issues, including without limitation protocols, endpoints and number of patients; provided that a decision on the matter would not have a material effect on the Development Costs and (ii) any dispute concerning the JDC's refusal to approve Phase IIA Clinical Trials or Phase IIB Clinical Trials proposed by Regeneron pursuant to Section 2.4.

10.3 Legal Disputes. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the commencement of the Term by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute, the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise.

10.4 Expert Panel. In the event of a dispute by the Parties concerning a Technical Development Matter that cannot be resolved by the Executive Officers pursuant to Section 3.12(b) (other than a Legal Dispute or any dispute concerning any proposed amendment of the Initial Co-Development Plan), either Party may by written notice to the other party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4. Such notice shall contain

a statement of the issue forming the basis of the dispute and the position of the moving Party as to the proper resolution of that issue. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question and of its position as to the proper resolution of that issue. Within twenty (20) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue, (ii) is not a director, employee or consultant of, or otherwise receiving compensation or other payments from such Party, and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above and that, as a member of the Expert Panel, such individual is able to render an independent decision. Each Party shall, within the same twenty (20) day period, provide its designated expert with a list of three (3) additional experts in the biotechnology industry and the specific matters at issue who meet the same criteria as described above. Thereafter, the two (2) appointed experts shall select a third expert from the list of experts provided by the Parties. Each expert shall agree, prior to his or her appointment, to name such third expert, and hear the dispute, promptly and render a decision as soon as practicable thereafter. The experts shall not amend this Agreement, but shall seek to fashion a remedy consistent with the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

10.5 No Waiver. Nothing in this Article 10 shall prohibit either Party from seeking immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions of the other.

## **ARTICLE 11 TRADEMARKS AND CORPORATE LOGOS**

11.1 Corporate Logos. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.

11.2 Selection of Product Trademarks. The JCC shall select one or more Product Trademarks (including back-up trademarks) for each VEGF Product for use with respect to such VEGF Product. Each VEGF Product shall be promoted and sold in the Co-Commercialization Countries under the applicable Product Trademark(s) approved by the JCC.

11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, (a) Regeneron (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s) for the Regeneron VEGF Products, together with all associated domain names, trade dress, trade names, and service marks for the Regeneron VEGF Products in the United States, and all goodwill related thereto (the "Regeneron Trademarks"), and (b) Aventis (or its local Affiliates, as

appropriate) shall own and retain all right, title and interest in and to Product Trademark(s) for the Aventis VEGF Products, together with all associated domain names, trade names, trade dress, and service marks for the Aventis VEGF Products throughout the Territory and for Regeneron VEGF Products in all countries in the Territory other than the United States and all goodwill related thereto (the "Aventis Trademarks"). In the Co-Marketing Countries, (a) Aventis shall own and have the exclusive right to use the Product Trademarks for oncology, (b) Regeneron shall own and have the exclusive right to use the Product Trademarks for diseases of the eye and (c) for all other Therapeutic Areas, the JSC shall establish a process for selecting which Party shall own and retain the rights to the Product Trademark(s) for each such Therapeutic Area in each of clauses (a), (b) and (c) above, together with all associated domain names, trade dress, service marks and all goodwill related thereto.

#### 11.4 Prosecution and Maintenance of Product Trademarks.

(a) Regeneron will use Commercially Reasonable Efforts to prosecute and maintain the Regeneron Trademarks for the Regeneron VEGF Products in the United States. Notwithstanding the foregoing, in the event Regeneron elects not to prosecute or maintain any Regeneron Trademark in the United States, Aventis shall have the right to do so on behalf of Regeneron for use with the VEGF Products during the Term, subject to consultation and cooperation with Regeneron. The Parties agree that all Out-of-Pocket Costs incurred in connection with the prosecution and maintenance of Regeneron Trademarks by Regeneron in the United States during the Term shall be shared by the Parties as part of Shared Promotion Expenses.

(b) Aventis will use Commercially Reasonable Efforts to prosecute and maintain the Aventis Trademarks for the Aventis VEGF Products in the Territory, and the Regeneron Trademarks for the Regeneron VEGF Products in all countries in the Territory other than the United States. Notwithstanding the foregoing, in the event Aventis elects not to prosecute or maintain any Aventis Trademark in the Territory, or any Regeneron Trademark in any country in the Territory, Regeneron shall have the right to do so on behalf of Aventis for use with the VEGF Products during the Term, subject to consultation and cooperation with Aventis. The Parties agree that all Out-of-Pocket Costs incurred in connection with the prosecution and maintenance of Aventis Trademarks or the Regeneron Trademarks by Aventis in the Major Market Countries during the Term shall be shared by the Parties as part of Shared Promotion Expenses.

11.5 License to the VEGF Product Trademarks. Each Party hereby grants to the other Party a license to use its Product Trademark(s) for the VEGF Products in the Co-Commercialization Countries for the purposes of such Party's Co-Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Each Party's rights under this Section 11.5 may be sublicensed, but only to its Affiliates and permitted sublicensees for the purposes of, and subject to the terms and conditions of, this Agreement. Except as provided in this Agreement, neither Party shall have rights in or to the other Party's Product Trademarks or the goodwill pertaining thereto. Each Party shall utilize the other Party's Product Trademarks only on approved Promotional Materials or other approved product-related materials for the VEGF

Products for the purposes contemplated herein, and all use by a Party or its Affiliates or permitted sublicensees of the Product Trademark(s) of the other Party shall (a) be in accordance with (i) rules established by the JCC and (ii) quality standards established by the other Party which are reasonably necessary in order to preserve the validity and enforceability of its Product Trademark(s) and (b) inure to the sole benefit of the other Party for the purposes of trademark and trade name ownership, registration, enforcement and maintenance. Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the other Party's Product Trademark(s) for the VEGF Products or take any other action which damages or dilutes the rights to, or goodwill associated with, such Product Trademarks in the applicable Co-Commercialization Countries. Subject to Article 19, each Party agrees that upon termination or expiration of the Term, it will discontinue forthwith all use of the other Party's Product Trademark provided that each Party shall have the right to continue to use such other Party's Product Trademark for a maximum period of two (2) years thereafter solely to the extent necessary to exhaust existing inventory of VEGF Product containing such Product Trademark. Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or assigning any rights in the trademark, trade dress, service marks, copyrights and goodwill associated therewith referred to above in this Section 11.5.

11.6 Use of Corporate Names. Each Party (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include the other Party's name (or such other Party's local Affiliate's name) with equal prominence on materials exclusively related to each VEGF Product (including, without limitation, package inserts, packaging, trade packaging, samples, and all Promotional Materials used or distributed in connection with the applicable VEGF Product) in the Co-Commercialization Countries, unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to VEGF Products as well as non-VEGF Products, the prominence of the other Party's commensurate with the relative prominence of the VEGF Product in such materials. Accordingly, each Party grants to the other (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and on all Promotional Materials used or distributed in connection with the applicable VEGF Product in the Co-Commercialization Countries during the Term and thereafter for a maximum period of two (2) years thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging, and samples solely to the extent necessary to exhaust the existing inventory of VEGF Product and Promotional Materials containing such name or logo.

## **ARTICLE 12**

### **NEWLY CREATED INVENTIONS**

#### 12.1 Ownership of Newly Created Intellectual Property.

(a) Each Party shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and

copyrights) discovered, invented, authored or otherwise created solely by such Party, its employees, agents and consultants (“Sole Inventions”). Sole Inventions made solely by Aventis, its employees, agents and consultants are referred to herein as “Aventis Sole Inventions.” Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as “Regeneron Sole Inventions.” The Parties agree that nothing in this Agreement, and no use by a Party of the other Party’s Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party’s Intellectual Property, other than the license rights expressly granted hereunder.

(b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Aventis (or for which ownership vests in Aventis by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron (or for which ownership vests in Regeneron by operation of law), on the other hand, on the basis of each Party having an undivided interest in the whole (“Joint Inventions”).

(c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Aventis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Aventis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Aventis Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

(d) To the extent that any right, title or interest in or to any intellectual property vests in a Party, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.

(e) The Parties hereby agree that each Party’s use of the Joint Inventions and other jointly owned intellectual property created under the Collaboration is governed by the terms and conditions of this Agreement, and with respect to use outside the scope of the Collaboration, shall be governed as follows: each Party’s interest in the Joint Inventions may be sublicensed, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party, provided that each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee’s written agreement to be bound by the terms of this Section 12.1(e); provided, further, that nothing in this Article 12 shall relieve a Party or

its Affiliates of their obligations under Article 16 with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense, or other exploitation of the Joint Inventions. Each of the Parties, as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the joint owner, such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

#### 12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights throughout the Territory, and shall confer with and keep Aventis reasonably informed regarding the status of such activities through the IPSC. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents included in the Regeneron Patent Rights: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Aventis review and comment with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and consider in good faith any comment; (ii) Regeneron shall notify the Aventis prior to the filing of a Patent Application by Regeneron; (iii) Regeneron shall consult with the Aventis promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) Regeneron shall provide Aventis promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) Regeneron shall provide Aventis, a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that Aventis has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights, Regeneron shall provide reasonable prior written notice to Aventis of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and Aventis shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Regeneron's name, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Aventis that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret.

(b) Aventis shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Aventis Patent Rights throughout the Territory, and shall confer with and keep Regeneron reasonably informed regarding the status of such activities through the IPSC. In addition, Aventis shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents included in the Aventis' Patent Rights: (i) Aventis shall use Commercially Reasonable Efforts to provide to Regeneron review and comment with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by Aventis and consider in good faith any comment; (ii) Aventis shall notify Regeneron prior to the filing of a Patent Application by Aventis; (iii) Aventis shall consult with Regeneron promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) Regeneron shall provide Aventis promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) Aventis shall provide Regeneron a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that y has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that Aventis desires to abandon any Patent included in the Aventis Patent Rights, Aventis shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Aventis Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Aventis' name, unless, with respect to any such Patent Applications that are unpublished, Aventis notifies Regeneron that Aventis would prefer to maintain the subject matter of such Patent Application as a trade secret.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall use Commercially Reasonable Efforts to provide to the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and consider in good faith any comment; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv)

the Controlling Party shall provide the non-Controlling Party promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) the Controlling Party shall provide the non-Controlling Party, a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within ninety (90) days of a written request by the non-Controlling Party to do so, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior notice to the other Party, providing a free-of-charge option to assume the prosecution or maintenance thereof.

(d) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Aventis Patent Rights, Regeneron Patent Rights and Joint Patent Rights, and any extensions pursuant to 12.2(e), shall be treated as a Shared Promotion Expense shared between the Parties as set forth herein.

(e) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The IPSC shall recommend to the JSC which of the Aventis Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term. Upon confirmation of the recommendation of the IPSC with respect to patent term extension by the JSC, the selected Party will file for said patent term extension.

### 12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition, or reexamination relating to Regeneron Patent Rights, Aventis Patent Rights, or Joint Patent Rights in the Territory. The Parties, through the IPSC, will thereafter consult and cooperate fully to determine a course of action with respect to any

such proceeding. Decisions on whether to initiate such a proceeding and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Aventis through the IPSC, (ii) with respect to Aventis Patent Rights, by Aventis in consultation with Regeneron through the IPSC, and (iii) with respect to Joint Patent Rights, jointly by the Parties through the IPSC.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue, or reexamination proceeding relating to the Regeneron Patent Rights, Aventis Patent Rights and/or Joint Patent Rights shall be treated as a Shared Promotion Expenses shared between the Parties as set forth herein.

### **ARTICLE 13 INTELLECTUAL PROPERTY LITIGATION**

#### 13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an infringement of a Aventis Patent Right, a Regeneron Patent Right, a Joint Patent Right, trademarks, copyrights or any other intellectual property right jointly owned or licensed under this Agreement by a Third Party's activities in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the IPSC to meet and consider the appropriate course of action with respect to such infringement.

(b) With respect to any infringement by virtue of a Third Party's activities, (i) Regeneron shall have the first right to bring and control any action or proceeding with respect to infringement of any Regeneron Patent Right or of any Joint Patent Right that primarily claims VEGF Trap or a Regeneron VEGF Product (or the making or use thereof), and (ii) Aventis shall have the first right to bring and control any action or proceeding with respect to infringement of any Aventis Patent Right or Joint Patent Right other than a Joint Patent Right that primarily claims VEGF Trap or a Regeneron VEGF Product (or the making or use thereof) (the Party with the first right being referred to as the "Lead Litigation Party"); provided, however, that the Parties shall ensure that there is proper communication and coordination of activities between the parties through the IPSC. If the Lead Litigation Party fails to bring any such action or proceeding with respect to infringement of the applicable Patent Right by a Third Party within sixty (60) days following notice of the alleged infringement, the non-Lead Litigation Party shall have the right to bring and control any such action at its own expense (the Party who controls the litigation to be referred to as the "Litigation Party"). The non-Litigation Party will provide reasonable assistance to the Litigation Party in prosecuting any suit, and if required by law, will join in the suit. Although the Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party through the IPSC and consider in good faith the recommendations of the other Party. The non-Litigation Party shall have the right to (and if required by law, will) join

in any litigation using counsel of its choice at its sole discretion and expense, subject to Section 13.1(c). The amount of any recovery from any such infringement suit shall be shared equally by the Parties.

(c) All Out-of-Pocket Costs (except for the expenses of the non-Litigation Party's counsel, if any) incurred in connection with any litigation under Section 13.1(b) shall be treated as Shared Promotion Expenses shared between the Parties as set forth herein.

13.2 Patent Marking. Each Party shall comply with the patent marking statutes in each county in which a VEGF Product is made, offered for sale, sold or imported by such Party, its Affiliates and/or sublicensees.

### 13.3 Third Party Infringement Claims.

(a) If either Party or its Affiliates (i) shall learn of a claim or assertion that the manufacture, Development or Commercialization of any VEGF Product infringes or otherwise violates the intellectual property rights of any Third Party in the Territory or (ii) learns of any allegations of alleged Patent invalidity or non-infringement of a Regeneron Patent Right, Aventis Patent Right or Joint Patent Right or any VEGF Product pursuant to a Paragraph IV Patent Certification or equivalent certification by a party filing for an approval of a generic product, then, in each case, such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the IPSC to meet and consider the appropriate course of action with respect to such allegation of infringement.

(b) If only one Party defends any claimed infringement action commenced by a Third Party alleging that the manufacture, Development or Commercialization of any VEGF Product infringes or otherwise violates the intellectual property rights of such Third Party in the Territory, the other Party and its Affiliates shall assist and cooperate in any such infringement litigation at the defending Party's (or its Affiliates') reasonable request.

(c) All Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation under this Section 13.3 shall be treated as Shared Promotion Expenses shared between the Parties as set forth herein.

## **ARTICLE 14 BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS**

14.1 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the

Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

#### 14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its costs), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided under this Agreement, including, without limitation, the numbers of FTEs and, in the case of sales representatives responsible for selling VEGF Products, the information with respect to such sales representatives' incentive compensation structure relating to such sales required by Section 6.3(b) to be included in a Country Co-Commercialization Plan and Country Co-Commercialization Budget, as applicable, the reports and payments provided under this Agreement and corresponding provisions of the Ancillary Agreements; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

(b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to the dispute resolution procedures set forth in Section 10.2. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than ten percent (10%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 16.

(c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party (or its Affiliate) owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party (or its Affiliate) entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 GAAP. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with GAAP as generally and consistently applied.

**ARTICLE 15  
REPRESENTATIONS AND WARRANTIES**

15.1 Due Organization, Valid Existence and Due Authorization. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article 4 hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.

15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any governmental entity or arbitrator that, individually or in the aggregate, could reasonably be expected to (i) materially impair the ability of such Party to perform any of its obligations under this Agreement or (ii) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

15.3 Additional Regeneron Representations and Warranties. Regeneron additionally represents and warrants to Aventis that, as of the Effective Date:

(a) Regeneron has not previously granted and will not grant any rights that conflict with the rights and licenses granted herein;

(b) to Regeneron's knowledge, [\*\*\*\*\*], there are no blocking Patents of a Third Party that would reasonably be expected to prevent the manufacture, use or sale of VEGF Trap as it is manufactured, used and sold by Regeneron as of the Effective Date;

(c) Regeneron is the sole owner of Regeneron's Patent Applications set forth on Schedule 15.3(c), to Regeneron's knowledge, free and clear of all liens, security interests and other encumbrances (other than unilateral creditor filings, as to

which this representation and warranty is made only to Regeneron's knowledge), and no Third Party has any right, title or interest in the Territory with respect to the Regeneron Patent Applications set forth on Schedule 15.3(c);

(d) It has no knowledge, [\*\*\*\*\*], that the making, using or selling of VEGF Trap as a pharmaceutical product would infringe the Patents of any Third Party in the Territory, nor does it have knowledge that any Third Party is infringing or misappropriating any of the Regeneron Intellectual Property;

(e) There are no judgments or settlements against or owed by Regeneron with respect to the Regeneron Intellectual Property owned by Regeneron;

(f) Except as otherwise set forth on Schedule 15.3(f), there are no claims, announced investigations, actions or other proceedings pending before or, to Regeneron's knowledge, threatened by any Regulatory Authority or other government agency with respect to VEGF Trap, any Regeneron facility or, to Regeneron's knowledge, any other facility where VEGF Trap is manufactured, and Regeneron has not received written notice threatening any such claim investigation, action or other proceeding. During the Term, Regeneron shall promptly notify Aventis in writing upon learning of any such actual or threatened claim, investigation, action or proceeding;

(g) To the knowledge of Regeneron, the development and manufacture of VEGF Trap has been conducted by Regeneron and its Affiliates and its subcontractors in compliance in all material respects with all applicable Laws, rules and regulations, and none of Regeneron or, to the knowledge of Regeneron, any of its Affiliates or subcontractors have received any notice in writing, or otherwise has knowledge of any facts, which have, or reasonably should have, led Regeneron to believe that any of the INDs relating to VEGF Trap are not currently in good standing with, the FDA;

(h) To Regeneron's knowledge, neither Regeneron, nor any officer, employee or agent of Regeneron, has made an untrue statement of a material fact to any Regulatory Authority with respect to VEGF Trap (whether in any submission to such Regulatory Authority or otherwise), or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to VEGF Trap;

(i) To Regeneron's knowledge, Regeneron and its employees, agents, clinical institutions and clinical investigators have materially complied with all FDA statutory and regulatory requirements with respect to VEGF Trap;

(j) Each Existing License is, to Regeneron's knowledge, in full force and effect as of the Effective Date. Regeneron has provided, to the extent contractually permitted, a true and complete copy of each Existing License to Aventis. Regeneron will devote commercially reasonable efforts to maintain the Existing Licenses in full force and effect and to perform its obligations thereunder and to keep Aventis informed of any material development pertaining thereto that would reasonably be expected to have a material adverse effect on Aventis' rights under this Agreement. Regeneron shall not, without the prior written approval of Aventis (i) amend any provision of an Existing

License that would reasonably be expected to have a material adverse effect on Aventis' rights under this Agreement or (ii) make any election or exercise any right or option to terminate in whole or in part any Existing License to the extent such election or exercise would reasonably be expected to have a material adverse effect on Aventis' rights under this Agreement; and

(k) Regeneron has made available to Aventis, to the extent material: (i) written preclinical and clinical study results and protocols for VEGF Trap, (ii) written communications to and from the FDA with respect to VEGF Trap, including but not limited to IND and BLA submissions, FDA minutes of meetings and telephone conferences, (iii) written FDA requests for data and studies with respect to the VEGF Trap, and (iv) written reports of adverse drug experiences and other IND safety reports with respect to the VEGF Trap .

15.4 Additional Aventis Representation and Warranty. Aventis additionally represents and warrants to Regeneron that as of the Effective Date, to Aventis' knowledge, Aventis is sponsoring [\*\*\*\*\*] in the United States.

15.5 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY VEGF PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

## **ARTICLE 16 CONFIDENTIALITY**

### 16.1 Confidential Party Information.

(a) Each of Aventis and Regeneron acknowledges (subject to Section 16.1(b) and Article 19) that all Party Information provided by, or discovered, invented, authorized or otherwise created by the other Party or its respective Affiliates pursuant to this Agreement is confidential and proprietary to such other Party or its respective Affiliates, and each of Aventis and Regeneron agrees to (i) maintain such Party Information and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Aventis and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such information to any Third Party except to its employees, agents or any other Person under its authorization; provided such employees, agents or Persons are subject in writing to substantially the same confidentiality obligations as the Parties.

(b) Notwithstanding anything provided above, the restrictions provided in this Article 16 shall not apply to information that is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or any Person to whom the receiving party provided such information; (ii) with respect to Party Information other than New Information is or was already in the possession of the receiving Party at the time of disclosure by the disclosing Party; (iii) is disclosed to the receiving Party on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) information that is similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid application or use of the confidential Party Information or New Information; or (v) required by Law to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information, and provided further that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Law to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement or any Ancillary Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

(c) Notwithstanding anything provided above, (i) [\*\*\*\*\*] any New Information and/or Regeneron's Party Information directly related to the Regeneron VEGF Products (including the making or use thereof) for use in its manufacture, Development and Commercialization of the Regeneron VEGF Products [\*\*\*\*\*]; provided, however, that any such disclosure of information shall be subject to confidentiality obligations on the part of such licensee substantially similar to those set forth herein; and (ii) Aventis shall have the right to disclose to any Aventis licensee of Aventis VEGF Products [\*\*\*\*\*] any of Regeneron's Party Information directly related to the Aventis VEGF Products, which is requested by such licensee for use in its Development of the Aventis VEGF Products [\*\*\*\*\*]; provided, however, that any such disclosure of information shall be subject to confidentiality obligations on the part of such licensee substantially similar to those set forth herein.

(d) Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any party) relating to such tax treatment or tax structure, provided, however, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws. This authorization of disclosure is retroactively effective

immediately upon commencement of the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than thirty (30) days from the first day that any Party hereto (or any employee, representative, or other agent of any party hereto) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.

16.2 Injunctive Relief. Each Party acknowledges that damages resulting from breach of this Article 16 would be an inadequate remedy and that, notwithstanding the provisions of Article 10, in the event of any such disclosure or any indication of an intent to disclose such information, a Party (or its Affiliates) owning such Party Information or New Information shall be entitled to seek, by way of private litigation, injunctive relief or other equitable relief in addition to any and all remedies available at law or in equity, including the recovery of damages and reasonable attorneys' fees, and in any such action for equitable relief in a court of competent jurisdiction, the Parties will not assert as a defense that there is an adequate remedy at law.

16.3 Publication of New Information. During the Term, if either Aventis or Regeneron (the "Publishing Party") desires to disclose any New Information or such other Party Information which relates to any VEGF Product in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information or such other Party Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve the New Information or such other Party Information, and the incorporation of such recommended changes shall not be unreasonably refused. If such other Party informs the Publishing Party, within thirty (30) days of receipt of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment should not be published or presented, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved. Disputes concerning publication shall be resolved by the JSC.

16.4 Other Publications. The Parties will mutually agree upon the contents of a joint press release which shall be issued simultaneously by both Parties upon the Effective Date. During the Term, Aventis and Regeneron agree not to (and to ensure that their respective Affiliates do not do so) issue any other press releases or public announcements concerning this Agreement or any Ancillary Agreement or any other activities contemplated thereunder without the prior written consent of the other Party to the form, timing and content of any such release or announcement, except as required by a Governmental Authority or applicable Law, and, subject to the further provisions of this Section 16.4, each Party agrees to provide to the other Party a copy of any public announcement, as soon as reasonably practicable (which, except under extraordinary circumstances, shall be at least five (5) Business Days) prior to its scheduled release;

provided, however, that, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any Ancillary Agreement or any activities contemplated thereunder which information was included in a press release or public announcement which was previously approved by the other Party as part of a press release or other public disclosure concerning this Agreement or which contains only non-material factual (non-financial) information regarding the Collaboration (e.g., that the Collaboration is ongoing in accordance with the terms of this Agreement). Except as otherwise required by applicable Law, the Party whose press release has been reviewed shall remove any information the reviewing Party reasonably deems to be inappropriate for disclosure. Neither Party shall unreasonably withhold or delay its consent to any such press release or announcement. Except as required by Law, or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 16 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse at least equivalent in scope to those included herein. In furtherance of the foregoing provisions of this Section 16.4, each Party shall give the other Party a reasonable opportunity to review all filings of this Agreement and all filings describing the terms of this Agreement with any Governmental Authority, including without limitation the United States Securities and Exchange Commission, prior to submission of such filings, and shall give due consideration to any reasonable comments by the non-filing Party relating to such filing, including without limitation the provisions of this Agreement for which confidential treatment should be sought.

## **ARTICLE 17 INDEMNITY**

### 17.1 Indemnity and Insurance.

(a) Aventis will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees and agents (“Regeneron Indemnitees”) from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys’ fees and costs (collectively, “Damages”), arising from or occurring as a result of a Third Party’s claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Aventis or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, distributors, representatives or other persons or entities working on their behalf), including, without limitation, in connection with the Development, Co-Commercialization, or manufacture of any VEGF Product, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates (or, to the extent permitted

under this Agreement, their respective agents, contractors, representatives or other persons or entities working on their behalf); or

(ii) material breach by Aventis (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Aventis would be a breach by the Aventis) of the terms of, or the representations and warranties made by it in, this Agreement or any applicable Ancillary Agreement to which it is a party.

(b) Regeneron will defend, indemnify and hold harmless Aventis, its Affiliates and their respective officers, directors, employees and agents (“Aventis Indemnitees”) from and against all Damages arising from or occurring as a result of a Third Party’s claim, action, suit, judgment or settlement against a Aventis Indemnitee that is due to or based upon:

(i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, distributors, representatives or other persons or entities working on their behalf), including, without limitation, in connection with the Development, Commercialization, or manufacture of any VEGF Product, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Aventis or its Affiliates (or, to the extent permitted under this Agreement, their respective agents, contractors, representatives or other persons or entities working on their behalf); or

(ii) material breach by Regeneron (or conduct or omission by any of its Affiliates, which if performed or failed to be performed by Regeneron would be a breach by Regeneron) of the terms of, or the representations and warranties made by it in, this Agreement or any applicable Ancillary Agreement to which it is a party.

(c) In the event of any product liability or other Third Party claim in a Major Market Country for which neither Party is entitled to indemnification hereunder, the Parties shall treat Damages therefrom as Shared Promotion Expenses.

(d) Each of Regeneron and Aventis will use Commercially Reasonable Efforts to procure and maintain during the Term and for a minimum period of five (5) years thereafter and for an otherwise longer period as may be required by applicable Law in countries where the project is conducted, product liability insurance in an amount not less than Ten Million Dollars (\$10,000,000) in the annual aggregate. Such insurance shall insure against liability on the part of Regeneron and Aventis and any of its Affiliates, due to injury, disability or death of any person or persons, or property damage arising from services performed under this Agreement.

17.2 Indemnity Procedure.

(a) The Party entitled to indemnification under this Article 17 (an “Indemnified Party”) shall notify the Party potentially responsible for such indemnification (the “Indemnifying Party”) within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.

(i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party’s responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days’ prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

(ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.

(iii) The amount of any Damages for which indemnification is provided under this Article 17 will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any Damages.

(iv) If an Indemnified Party receives an indemnification payment pursuant to this Article 17 and subsequently receives insurance proceeds from its insurer with respect to the damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article 17 and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article 17.

## **ARTICLE 18 FORCE MAJEURE**

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement or any Ancillary Agreement for failure or delay in fulfilling or performing any term of this Agreement or any Ancillary Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

## **ARTICLE 19 TERM AND TERMINATION**

### 19.1 Term/Expiration of Term.

(a) The "Term" of this Agreement shall commence on the Effective Date and end at such time as neither Party, nor either Party's Affiliates or sublicensees, is Developing or Commercializing any VEGF Product anywhere in the Territory (and such cessation of Development and Commercialization activities is acknowledged by both Parties to be permanent), unless earlier terminated as provided hereafter.

(b) Upon expiration of the Term, all licenses and rights with respect to VEGF Products shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause. Aventis may terminate this Agreement with respect to the entire Territory for all VEGF Products on twelve (12) months' prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2, the Agreement shall continue in full force and effect through the notice period set forth above (the "Termination Notice Period"). Upon expiration of the Termination Notice Period, or earlier to the extent provided below in this Section 19.2, all licenses and rights granted to Aventis hereunder shall automatically terminate and revert to Regeneron (except to the extent required by Aventis to fulfill its obligations pursuant to Part A of Schedule 8, and upon the earlier of such fulfillment or written notice from Regeneron that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), and the provisions of Part A of Schedule 8 shall apply. During the Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Aventis hereunder (i) such licenses and rights granted to Aventis shall automatically terminate as of a date specified in such notice(s) (but not later than the Termination Notice Period) and (ii) Aventis will promptly take the actions required by Part A of Schedule 8 and Regeneron will reasonably cooperate with Company (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Termination Notice Period, with as little disruption as reasonably possible, of the continued Development and/or Commercialization of such VEGF Product(s). In addition, during the Termination Notice Period (i) Company shall have no obligation to pay to Regeneron any of the milestone payments listed on Schedule 2 for any Milestone events that occur during the Termination Notice Period, except for the \$25,000,000 Milestone payment designated on Schedule 2 as milestone Number "1" if such Milestone event occurs during such period and (ii) Regeneron shall not without the prior written consent of the applicable Committee or Sub-Committee propose or implement any amendment or change to any Co-Development Plan, Co-Development Budget, Country Co-Commercialization Plan, Country Co-Commercialization Budget, Global Co-Commercialization Plan or Global Co-Commercialization Budget.

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using diligent efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use diligent efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period

referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term “material breach” shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the non-breaching Party from the Collaboration, taken as a whole.

19.4 Termination for Insolvency. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (i) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (ii) if the other Party proposes a written agreement of composition or extension of its debts, or (iii) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (iv) if the other Party shall propose or be a party to any dissolution or liquidation, or (v) if the other Party shall make an assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party’s bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to “intellectual property” as defined under Section 101(52) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the “intellectual property” as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, upon written notice to Aventis, if Aventis shall have breached Section 20.16 of this Agreement. For the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of an inadvertent breach of Section 20.16(g) arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 20.16.

19.6 Termination for Breach of Stock Purchase Lock-Up. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, upon written notice to Aventis, if Aventis shall have materially breached Section 5.3 of the Stock Purchase Agreement.

19.7 Effect of Termination/Expiration.

(a) Except as set forth in Section 19.7(b) below, upon termination of this Agreement, the provisions of Part A of Schedule 8 shall apply, and except to the

extent required by Aventis to fulfill its obligations pursuant to Part A of Schedule 8 (and upon the earlier of such fulfillment or written notice from Regeneron that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Regeneron), (i) all licenses and rights granted by Regeneron to Aventis hereunder with respect to any terminated country and VEGF Product shall automatically terminate and revert to Regeneron, and (ii) the licenses from Aventis and its Affiliates to Regeneron referred to in Part A of Schedule 8 shall come into full force and effect.

(b) Upon termination of this Agreement by Aventis pursuant to Section 19.3 or 19.4, the provisions of Part B of Schedule 8 shall apply with respect to Aventis VEGF Products, and except to the extent required by Regeneron to fulfill its obligations pursuant to Part B of Schedule 8 (and upon the earlier of such fulfillment or written notice from Aventis that it will not require such fulfillment, such licenses and rights, to the extent not previously terminated, shall automatically terminate and revert to Aventis), (i) all licenses and rights granted by Aventis to Regeneron hereunder with respect to the Aventis Products and any other Aventis VEGF Products shall automatically terminate and revert to Aventis, and (ii) the licenses from Regeneron to Aventis referred to in Part B of Schedule 8 shall come into full force and effect for the Aventis VEGF Products.

19.8 Survival of Obligations. Except as otherwise provided in this Article 19, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate to the extent of such expiration or termination, and this Agreement shall cease to be of further force or effect to the extent of such expiration or termination, provided that notwithstanding any expiration or termination of this Agreement: (i) neither Aventis nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of an approved Co-Development Plan, Global Co-Commercialization Plan, Joint Country Commercialization Plan or Manufacturing Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that (A) in the case of termination of this Agreement pursuant to Section 19.2, without limitation of and subject to Aventis' continuing obligations under the provisions referred to in clause (ii) of Section 19.2, Aventis' other obligations hereunder shall terminate prior to expiration of the Termination Notice Period if prior to such expiration Regeneron enters into a collaboration agreement of substantially similar scope as, and providing for the assumption and performance by the counterparty thereto of the obligations of Aventis under, this Agreement and (B) notwithstanding any other term or provision of this Agreement, upon termination of this Agreement for any reason, Regeneron's obligation with respect to Development Payments provided for in Schedule 1 shall automatically terminate; (ii) subject to the provisions of this Article 19 (including Schedule 8 to the extent applicable), the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article 16, as well as other provisions (including, without limitation, Sections 2.7, 6.18, 7.2(b), 7.5, 7.6, 7.7, 7.8, 7.9, 11.5, 11.6, and Articles 9, 12, 14, 17, 19 (including Schedule 8), and 20 to the extent applicable) which by their nature are

intended to survive any such expiration or termination, shall survive and continue to be enforceable; and (iii) such expiration or termination and this Article 19 shall be without prejudice to any rights or remedies a party may have for breach of this Agreement, including, without limitation, any breach of the provisions referred to in clause (ii) above.

**ARTICLE 20**  
**MISCELLANEOUS**

20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to conflict of laws principles. Each Party hereby irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit or proceeding arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts.

20.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

20.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 9 attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service, or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

20.4 Entire Agreement. This Agreement together with the Ancillary Agreements to the extent referred to herein contains the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof.

20.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Aventis and Regeneron.

20.6 Headings. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.

20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction, provided, further that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

20.8 Registration and Filing of the Agreement. To the extent that a Party concludes in good faith that it is required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4 above. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.

20.9 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Aventis or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Aventis or (b) the prior written consent of Aventis in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) subject to Section 19.5, to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

20.11 Affiliates. Each Party may perform its obligations hereunder through one or more of its Affiliates, although each Party shall nonetheless be responsible for the performance of its Affiliates. Neither Party shall permit any of its Affiliates to commit

any act (including any act or omission) which such Party is prohibited hereunder from committing directly.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

20.13 Third-Party Beneficiaries. Except as provided below in this Section 20.13, none of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article 17 is intended to benefit, and to be enforceable by, in addition to the Parties, the other Regeneron Indemnitees and Aventis Indemnitees as if they were parties hereto.

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Aventis nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Aventis, and Aventis' legal relationship under this Agreement to Regeneron, shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR AVENTIS BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE PAID TO A THIRD PARTY AS PART OF A THIRD-PARTY CLAIM WHICH IS COVERED BY THE INDEMNIFICATION OBLIGATIONS IN ARTICLE 17.

20.16 Standstill Agreement. During the Term and for a period of five (5) years thereafter, neither Aventis nor any of its Affiliate (for purposes of this Section 20.16, Aventis, together with such Affiliates, being referred to as the "Investor") shall:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock or any securities convertible into or exchangeable for Shares of Then Outstanding Capital Stock, or make a tender, exchange or other offer to

acquire Shares of Then Outstanding Capital Stock, if after giving effect to such acquisition (and assuming the conversion of all convertible securities), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act) twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted in Investor's ownership totaling twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock;

(b) directly or indirectly, propose or nominate for election to the Board of Directors of Regeneron any Person whose nomination has not been approved by a majority of the Board of Directors of Regeneron, or vote or cause to be voted in favor of such Person for election to the Board of Directors of Regeneron any Shares of Then Outstanding Capital Stock;

(c) directly or indirectly, encourage or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of Regeneron (an "Acquisition Proposal");

(d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Securities Exchange Act) in opposition to the recommendation of a majority of the Board of Directors of Regeneron with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Capital Stock of Regeneron or any of its Affiliates;

(e) deposit any Shares of Then Outstanding Capital Stock in a voting trust or subject any Shares of Then Outstanding Capital Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Capital Stock;

(f) act in concert with any Third Party to take any action in clauses (a) through (e) above;

(g) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in (a) through (e) above; or

(h) request or propose that Regeneron or any of Regeneron's officers or its Board of Directors amend, waive, or consider the amendment or waiver of any provisions set forth in this Section 20.16;

provided that the mere voting of any Shares of Then Outstanding Capital Stock held by the Aventis shall not constitute a violation of any of clauses (a) through (f) above.

20.17 Termination of Standstill. Provided Investor has not violated Section 20.16(d) or (f) with respect to the Offeror referred to in this Section 20.17, the restrictions contained in Section 20.16 shall terminate upon the earlier to occur of (i) the public

announcement by an Offeror of an Acquisition Proposal; (ii) the acquisition by an Offeror (other than Dr. Leonard Schleifer or his Affiliate) of beneficial ownership of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by the Offeror, represents more than [\*\*\*\*\*] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock; or (iii) the issuance by Regeneron to a Third Party of Shares of Then Outstanding Capital Stock, which, when combined with all other Shares of Then Outstanding Capital Stock beneficially owned by such third party, represents more than [\*\*\*\*\*] of the voting power represented by all issued and outstanding Shares of Then Outstanding Capital Stock, if Regeneron does not enter into a standstill agreement for a time period and upon terms substantially similar to the provisions of this Section 20.17; (iv) a sale of all or substantially all of the assets of Regeneron (other than to a wholly owned subsidiary of Regeneron); or (v) a liquidation or dissolution of Regeneron, which would give rise to a termination of this Agreement pursuant to Section 19.4; provided, however, that if any of the transactions referred to in (i), (ii) or (iv) above terminates and Regeneron has not made a public announcement of its intent to solicit or engage in a transaction referred to in 20.16 (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of Regeneron, then the restrictions contained in Section 20.16 shall again be applicable.

20.18 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employees from the other Party involved in the manufacture, Development, Co-Promotion or Co-Marketing of any VEGF Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

IN WITNESS WHEREOF, Aventis and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

COMPANY

By /s/ Gerald P. Belle

\_\_\_\_\_  
Name: Gerald P. Belle  
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray Goldberg

\_\_\_\_\_  
Name: Murray A. Goldberg  
Title: Senior Vice President,  
Finance & Administration

SCHEDULE 1.101

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SCHEDULE 1

Quarterly True-Up

The true-up in a calendar quarter (the “Quarterly True-Up”) shall be equal to the sum of the Major Market True-Up (as set forth in Part I), plus the Rest of World True-Up (as set forth in Part II), plus the Regeneron Development Reimbursement Amount (as set forth in Part III), less the Development Payment (commencing in the calendar quarter of the First Commercial Sale of a VEGF Product in any country in the Territory) (as set forth in Part IV). In the event that the Quarterly True-Up is an amount greater than zero, such amount will be payable by Aventis to Regeneron in accordance with the terms set forth in Section 9.3. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Aventis in accordance with the terms set forth in Section 9.3. An example of the Quarterly True-up is shown in Part V.

I. MAJOR MARKET TRUE-UP

The “Major Market True-Up” shall mean the Major Market Profit Split, plus 100% of Shared Promotion Expenses incurred by Regeneron. The “Major Market Profit Split” shall mean the product of (x) aggregate Net Sales in Major Market Countries less aggregate VEGF Product Expenses, and (y) .50. “VEGF Product Expenses” shall mean the sum of COGS and Shared Promotion Expenses incurred by both Parties for such calendar quarter. For the avoidance of doubt, the Major Market Profit Split shall apply independent of the detailing effort provided by either Party, such that, for example, if Regeneron provided none of the detailing efforts, it will still be entitled to 50% of the sum of aggregate Net Sales in the Major Market Countries less aggregate VEGF Product Expenses in Major Market Countries.

An example of a calculation for a Major Market True-Up would be:

	<u>Aggregate</u>	<u>Aventis 50%</u>	<u>Regeneron 50%</u>
Net Sales in Major Market Countries	1000	1000	
VEGF Product Expenses:			
• COGS	(100)	(100)	(0)
• Shared Promotion Expenses	(500)	(400)	(100)
income or expenses incurred	400	500	(100)
Major Market Profit-Split		200	200
Major Market True-Up		(300)	300

II. REST OF WORLD TRUE-UP

The “Rest of World True-Up” shall mean the Rest of World Profit Split plus 100% of Regeneron’s Sales Force Costs and Regeneron’s Medical Affairs Costs, in each case as it relates to a Rest of World Country. The “Rest of World Profit Split” shall mean the product of (x) [\*\*\*\*\*], and (z) .50.

An example of a calculation for a Rest of World True-Up would be:

	Aggregate	Aventis 50%	Regeneron 50%
Net Sales in Rest of World Countries	20	20	
Regeneron Sales Force Cost			(2)
Regeneron Medical Affairs Cost			(0)
[*****]	[**]		
Rest of World Profit Split	10	5	5
Rest of World True-Up		(7)	7

III. REGENERON DEVELOPMENT REIMBURSEMENT

The “Regeneron Development Reimbursement Amount” shall mean the aggregate amount of Development Costs incurred by Regeneron in such calendar quarter.

An example of the Regeneron Development Reimbursement Amount would be: 20

IV. DEVELOPMENT PAYMENT

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An example of a calculation of Development Payment would be:

	Aggregate	Aventis 50%	Regeneron 50%
[*****]	[**]	[**]	[**]
[*****]	[**]		
Development Payment	(10)	10	

## V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of Quarterly True-up would be:

Major Market True-up	=	300
Rest of World True-up	=	7
Regeneron Development Reimbursement Amount	=	20
Development Payment	=	(10)
Quarterly True-up	=	317

In this example, Aventis would pay Regeneron 317 in accordance with the terms set forth in Section 9.3.

SCHEDULE 2

Milestone Payments

Milestone

1	US \$25,000,000	[*****]
***	[*****]	[*****]
***	[*****]	[*****]
***	[*****]	[*****]
***	[*****]	[*****]
***	[*****]	[*****]
***	[*****]	[*****]
***	[*****]	[*****]
***	[*****]	[*****]

For purposes of clarification, each of the foregoing milestone payments shall be made only once and only upon the first occurrence of each milestone, regardless of the number of VEGF Products or occurrences of each milestone for VEGF Products [\*\*\*\*\*]. For purposes of further clarification, if one Marketing Approval in a Major Market Country covers two or more milestone payments, both (or all) of the applicable milestone payments shall be made. For purposes of clarification and as an example, only one milestone would be payable in the circumstance where [\*\*\*\*\*].

SCHEDULE 3

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SCHEDULE 5

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SCHEDULE 7

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## SCHEDULE 8

### Transition Arrangements

#### PART A of Schedule 8

\*\*As used in this Part A of Schedule 8, the term “VEGF Products” shall exclude Aventis VEGF Products if the Agreement is effectively terminated by Aventis pursuant to Section 19.3.

1. Aventis shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Regeneron or, at Regeneron’s request, destroy, all documents containing Party Information or New Information directly relating to the VEGF Products, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any such Party Information or New Information with respect to such VEGF Products. In addition, at Regeneron’s request, Aventis shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, product samples, and VEGF Product inventory. Notwithstanding the foregoing in this Part A of Schedule 8, Aventis may retain copies of any Party Information or New information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes. Regeneron shall be entitled to use and disclose any such information (including any such Party Information and/or New Information) in connection with the manufacture, Development or Commercialization of VEGF Products

2. Aventis shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development and/or Commercialization of the VEGF Products. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Regeneron shall have a fully paid-up and royalty-free exclusive license (which shall include the right to grant sublicenses) from Aventis under Aventis Patent Rights and Aventis Know-How existing at the effective date of termination that are used to Develop, make, have made, use, import, offer to sell and sell the VEGF Products as of the effective date of termination for use in connection with such activities.

(b) Aventis shall transfer and assign to Regeneron (or its nominee) all Approvals and regulatory filings (including Registration Filings) made or obtained by Aventis or its Affiliates or any of its sublicensees to the extent specifically relating to the VEGF Products (other than Approvals for Aventis manufacturing facilities). In addition, at Regeneron’s request, Aventis shall take all actions to revoke any appointment as Regeneron’s exclusive agent in the United States, including writing a letter to the applicable Governmental Authorities in the United States to revoke such appointment.

(c) Aventis shall assign and transfer to Regeneron (or its nominee) Aventis' entire right, title and interest in and to all Product Trademarks to the extent specifically relating to the VEGF Products and to any domain names containing such Product Trademarks; provided that nothing herein is intended to convey any rights in or to Aventis' corporate name and logos or any trade names.

(d) Aventis shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the manufacture, Development or Commercialization of the VEGF Products in the Territory of all information (including any Party Information and/or New Information)) in its possession or under its control to the extent directly relating to any VEGF Products, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Aventis, or such other format as may be reasonably requested by Regeneron.

(e) [\*\*\*\*\*]

(f) [\*\*\*\*\*]

(g) Without limitation of Aventis' other obligations under this Part A of Schedule 8, Aventis will take the actions required by subparagraph (g)(i) below to the extent it is responsible for supplying Commercial Requirements of such VEGF Product in such country pursuant to Article 8.

(i) Aventis will supply Regeneron with Clinical Supply Requirements and/or Commercial Requirements of finished and packaged VEGF Products at the same price, and on such other terms and conditions on which Aventis was supplying, or in the absence of termination, would have been required to supply such finished and packaged VEGF Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Aventis that it is able to manufacture or have manufactured VEGF Products on comparable financial terms.

(h) [\*\*\*\*\*] Regeneron shall have the right to acquire the Aventis Equipment on ninety days prior notice for a purchase price equal to the book value of the Aventis Equipment on the acquisition date. Such right shall be exercisable prior to the effective date of termination or, if paragraph (g)(i) of this Schedule 8 is applicable, prior to the earlier of (i) the second anniversary of such effective date or (ii) the date Aventis' completes its post-termination supply obligations. If Regeneron notifies Aventis that it will not exercise this purchase option, or fails to timely deliver a notice of its exercise of its right to purchase the Aventis Equipment, then Aventis shall have a reasonable period of time to remove the Aventis Equipment from Regeneron's facility and only upon reasonable advance notice. If the Aventis Equipment is used in connection with such post-termination supply obligations, Aventis shall not remove the Aventis Equipment until the completion of Aventis' post-termination supply obligations. Regeneron shall provide Aventis with reasonable access to its manufacturing facility to remove the Aventis Equipment pursuant to this paragraph (h) and, following

the removal, Aventis shall restore the space in the facility used to house the Aventis Equipment to its pre-installation condition.

3. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Co-Development and Co-Commercialization of the VEGF Products hereunder to Regeneron (or its sublicensee or third party designee) as soon as is reasonably possible.

4. For the avoidance of doubt, Regeneron shall not be required to provide Aventis any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Part A of Schedule 8; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Aventis may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights; and provided, further, that if Aventis continues to manufacture the VEGF Products in such terminated country pursuant to paragraph (g) above, Regeneron shall purchase such products at the price, and on such other terms and conditions specified therein.

#### PART B of Schedule 8

1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Aventis or, at Aventis' request, destroy, all documents containing Party Information or New Information directly relating to any Aventis VEGF Product in the terminated country, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any such Party Information or New Information with respect to such Aventis VEGF Products. Notwithstanding the foregoing in this Part B of Schedule 8, Regeneron may retain copies of any such information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes. Aventis shall be entitled to use and disclose any such information (including any such Party Information and/or New Information) in connection with the manufacture, Development, Commercialization, production of Aventis VEGF Products.

2. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Aventis to enable Aventis (or its nominee) to assume with as little disruption as reasonably possible, the continued Development and/or Commercialization of the Aventis VEGF Products. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:

(a) Aventis shall have a fully paid-up and royalty-free exclusive license (which shall include the right to grant sublicenses) from Regeneron under Regeneron Patent Rights and Regeneron Know-How existing at the effective date of termination that are used to Develop, make, have made, use, import, offer to sell and sell the terminated Aventis VEGF Products as of the effective date of termination for use in connection with such activities.

(b) Regeneron shall transfer and assign to Aventis (or its nominee) all Approvals and regulatory filings (including Registration Filings) made or obtained by Aventis or its Affiliates or any of its sublicensees to the extent relating to the terminated Aventis VEGF Products (other than Approvals for Regeneron manufacturing facilities).

(c) Regeneron shall assign and transfer to Aventis (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks to the extent relating to the Aventis VEGF Products and to any domain names containing such Product Trademarks; provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names.

(d) Regeneron shall provide to Aventis (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the manufacture, Development or Commercialization of the Aventis VEGF Products of all information (including any Party Information and/or New Information) in its possession or under its control to the extent directly relating to Aventis VEGF Products, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Aventis.

(e) [\*\*\*\*\*]

(f) [\*\*\*\*\*]

(g) Without limitation of Regeneron's other obligations under this Part B of Schedule 8, Regeneron will take the actions required by subparagraph (g)(i) below to the extent it is responsible for supplying Clinical Supply Requirements of such Aventis VEGF Product in such country pursuant to Article 8.

(i) Regeneron will supply Aventis with Clinical Supply Requirements of finished and packaged terminated Aventis VEGF Product at the same price, and on such other terms and conditions on, which Regeneron was supplying, or in the absence of termination, would have been required to supply such finished and packaged Aventis VEGF through the second anniversary of the effective date of termination of this Agreement or such shorter period if Aventis is able to manufacture or have manufactured its Clinical Supply Requirements.

3. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Co-Development and Co-Commercialization of the Aventis VEGF Product hereunder to Aventis (or its sublicensee or third party designee) as soon as is reasonably possible.

4. For the avoidance of doubt, except as set forth in paragraph 2(a) above, Aventis shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Part B of Schedule 8; provided, however, that Aventis shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Aventis of such licenses or other rights.

SCHEDULE 9

Notices

- (a) If to Aventis:  
200 Crossing Boulevard  
Bridgewater, New Jersey 08807  
U.S.A  
Attention: Vice President, Legal Corporate Development

With a copy to:

Morgan, Lewis, & Bockius, LLP  
502 Carnegie Center  
Princeton, New Jersey 08540  
Attention: Randall B. Sunberg

- (b) If to Regeneron:  
Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591  
U.S.A.  
Attention: President  
Copy: General Counsel

SCHEDULE 15.3(c)

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STOCK PURCHASE AGREEMENT

By and Between

AVENTIS PHARMACEUTICALS INC.

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of September 5, 2003

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## STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (“Agreement”), dated as of September 5, 2003, by and between AVENTIS PHARMACEUTICALS INC. (the “Investor”), a corporation organized under the laws of Delaware, with its principal place of business in the United States at 200 Crossing Boulevard, Bridgewater, New Jersey 08807, and REGENERON PHARMACEUTICALS, INC. (the “Company”), a corporation organized under the laws of New York with its principal place of business at 777 Old Saw Mill Road, Tarrytown, New York.

WHEREAS, concurrently with the execution of this Agreement, the Investor and the Company have entered into a Collaboration Agreement (the “Collaboration Agreement” and together with this Agreement, the “Transaction Agreements”); and

WHEREAS, it is contemplated by the Collaboration Agreement that the Investor purchase, and the Company issue and sell to the Investor, shares of common stock of the Company pursuant to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

### ARTICLE 1 DEFINITIONS

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

“Affiliate” shall mean, with respect to any Person, any other Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

“Business Day” shall mean any day other than a Saturday or Sunday or a day on which banks located in New York, New York are authorized or required by law to close.

“Common Stock” shall mean the Company’s Common Stock, par value \$0.001 per share. Common Stock shall not include shares of the Company’s class A shares.

“Company Intellectual Property” shall mean the Intellectual Property that is owned by Company and the Intellectual Property subject to an Intellectual Property License pursuant to which its use by the Company is permitted by any third party.

“Disposition” or “Dispose of” shall mean any (i) offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of the

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Company's common stock, par value \$.001 per share, or any securities convertible into or exchangeable or exercisable for such common stock or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Company's common stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

"Governmental Authority" shall mean any federal, state, municipal, local, provincial or regional governmental authority in the United States or other political subdivision thereof and any Person exercising executive, legislative, judicial regulatory or administrative functions of or pertaining to government.

"Intellectual Property" shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.

"Intellectual Property License" shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.

"Material Adverse Effect" shall mean any events, occurrences or circumstances which give rise to or would reasonably be expected to give rise to, individually or in the aggregate, a material adverse effect on the business, business prospects, properties, condition (financial or otherwise) or results of operations of the Company.

"Organizational Documents" shall mean the Company's Certificate of Incorporation as in effect on the date hereof and the Company's Bylaws as in effect on the date hereof.

"Person" shall mean and include an individual, a partnership, a joint venture, a corporation, a limited liability company, a limited liability partnership, a trust, an incorporated organization and a Governmental Authority.

1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Agreement	Preamble
Closing	2.2
Closing Date	2.2
Collaboration Agreement	Preamble
Company	Preamble
Company SEC Documents	3.10(a)
Exchange Act	3.10(a)
Investor	Preamble
Purchase Price	2.1
Purchased Stock	2.1

Defined Term	Section
Rule 144	5.2
SEC	3.6
Securities Act	3.10(a)
Severed Clause	6.10
Transaction Agreements	Preamble

1.3 Construction. In this Agreement, unless the context otherwise requires:

- (a) any reference in this Agreement to “writing” or comparable expressions includes a reference to facsimile transmission or comparable means of communication;
- (b) words expressed in the singular number shall include the plural and vice versa, words expressed in the masculine shall include the feminine and neuter gender and vice versa;
- (c) references to Articles and Sections are references to articles and sections of this Agreement;
- (d) reference to “day” or “days” are to calendar days; and
- (e) “include,” “includes,” and “including” are deemed to be followed by “without limitation” whether or not they are in fact followed by such words or words of similar import.

1.4 Knowledge. Where any representation or warranty contained in this Agreement is expressly qualified by reference to the knowledge of the Company, the Company confirms that it has made reasonable inquiry or investigation as to the matters that are the subject of such representations and warranty.

**ARTICLE 2  
PURCHASE AND SALE OF COMMON STOCK**

2.1 Issuance of Common Stock. Subject to the terms and conditions hereof, on the Closing Date, the Company agrees to issue and sell to the Investor, and the Investor agrees to purchase, 2,799,552 shares of Common Stock (the “Purchased Stock”) for an aggregate purchase price of \$45,000,000 (the “Purchase Price”). The price per share of the Purchased Stock shall be \$16.074, which amount represents the average daily closing price per share on the Nasdaq Stock Market during the five (5) trading days immediately preceding, but not including, the date of this Agreement.

2.2 Closing. The purchase and sale of the Purchased Stock (the “Closing”) shall occur on the date hereof at the offices of Skadden, Arps, Slate, Meagher & Flom LLP, at Four Times Square, New York, New York. The date on which the Closing occurs is referred to herein as the “Closing Date”.

2.3 Delivery. Within three (3) Business Days of the Closing Date, the Company shall deliver to the Investor a stock certificate, registered in the Investor’s name, representing the Purchased Stock. Within one (1) Business Day following the Closing Date, Investor shall

deliver to the Company the Purchase Price by wire transfer of same day funds to the Company's bank account as follows:

Beneficiary Name:	Regeneron Pharmaceuticals, Inc.
Beneficiary Address:	777 Old Saw Mill River Road Tarrytown, New York 10591
Account Number:	[*****]
Bank Name:	[*****]
Bank Address:	[*****] [*****]
Bank Clearing Number:	[*****]

**ARTICLE 3  
REPRESENTATIONS AND WARRANTIES OF THE COMPANY**

The Company hereby represents and warrants to the Investor as of the date hereof as follows:

3.1 Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. The Company has all requisite corporate power and corporate authority to own and operate its properties and assets, to carry on its business as now conducted and as proposed to be conducted in the Company SEC Documents, to enter into the Transaction Agreements, to issue and sell the Purchased Stock and to carry out the other transactions contemplated under the Transaction Agreements. The Company is qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by the Company or the nature of the business conducted by the Company makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

3.2 Capitalization and Voting Rights.

(a) The authorized capital of the Company as of September 4, 2003 consisted of: (i) 160,000,000 shares of Common Stock, par value \$0.001 per share, of which (w) 49,829,556 shares were issued and outstanding, (x) 2,403,848 shares were reserved for issuance upon conversion of the Company's class A stock, each share of class A stock being convertible into one share of Common Stock, (y) 15,265,493 shares were reserved for issuance pursuant to the Company's 1990 Long-Term Incentive Plan and 2000 Long-Term Incentive Plan and (z) 6,611,300 shares were reserved for issuance upon conversion of the Company's 5½% Convertible Senior Subordinated Notes due 2008, (ii) 40,000,000 shares of class A stock, par value \$0.001 per share, of which 2,403,848 shares were issued and outstanding, and (iii) 30,000,000 shares of preferred stock, par value \$0.01 per share, of which no shares were issued and outstanding. All of the issued and outstanding shares of Common Stock and class A stock have been duly authorized, and all of the issued and outstanding shares of Common Stock and class A stock have been validly issued, are fully paid and non-assessable, and were issued in compliance with all applicable federal and state securities laws.

(b) All of the authorized shares of Common Stock are entitled to one (1) vote per share. All of the authorized shares of class A stock are entitled to ten (10) votes per share.

(c) Except as set forth in the Company SEC Documents filed at least seventy-two (72) hours prior to the date of this Agreement, or as provided in the Transaction Agreements, there are not, nor upon the consummation of the transactions contemplated hereby shall there be: (i) any outstanding options, warrants, rights (including conversion or preemptive rights) or agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company and (ii) any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities laws.

(d) Except as set forth in the Company SEC Documents filed prior to the date of this Agreement or as provided in the Transaction Agreements, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a shareholder or director of the Company.

3.3 Subsidiaries. The Company does not have any subsidiaries required to be disclosed in Exhibit 21 to its annual report on Form 10-K.

3.4 Authorization. All corporate action on the part of the Company, its directors and stockholders necessary for the authorization, execution and delivery of the Transaction Agreements and the performance of all obligations of the Company thereunder, including the authorization, issuance and delivery of the Purchased Stock, has been taken. This Agreement has been duly executed and delivered by the Company and, upon due execution and delivery by Investor, constitutes a valid and legally binding obligation of the Company, enforceable against the Company in accordance with its terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

3.5 No Conflicts. The execution and performance of the Transaction Agreements and compliance with the provisions thereof by the Company, do not and shall not: (a) violate any provision of law, statute, ordinance, rule or regulation or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default (or an event which, with notice or lapse of time or both, would become a default) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound, or (c) violate or conflict with any of the provisions of the Company's Organizational Documents; except, in the case of subsections (a) and (b) as would not have a Material Adverse Effect.

3.6 No Governmental Authority or Third Party Consents. No consent, approval, authorization or other order of any Governmental Authority or other third party is required to be obtained by the Company in connection with the authorization, execution and delivery of this Agreement or with the authorization, issue and sale of the Purchased Stock, except such filings

as may be required to be made with the Securities and Exchange Commission (the "SEC") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable laws, rules, regulations, statutes, ordinances and orders.

3.7 Valid Issuance of Purchased Stock. When issued, sold and delivered in accordance with the terms hereof for the consideration expressed herein, the Purchased Stock shall be duly authorized, validly issued, fully paid and nonassessable, free from any encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than restrictions on transfer under the Transaction Agreements and under federal and state securities laws.

3.8 Litigation. There is no action, suit, proceeding or investigation pending or threatened against the Company or which the Company intends to initiate which (a) questions the validity of the Transaction Agreements or the right of the Company to enter into them, or to consummate the transactions contemplated thereby, or (b) except as set forth in the Company SEC Documents filed prior to the date of this Agreement, if determined adversely would have a Material Adverse Effect.

3.9 Licenses and Other Rights; Compliance with Laws. The Company has all franchises, permits, licenses and other rights and privileges necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a Material Adverse Effect. The Company is and has been in compliance with all laws and governmental rules and regulations applicable to its business, properties and assets, and to the products and services sold by it, including, without limitation, all such rules, laws and regulations relating to fair employment practices, occupational safety and health and public safety, except where the failure to be in compliance does not and would not have a Material Adverse Effect.

3.10 Company SEC Documents; Financial Statements; Nasdaq Stock Market.

(a) Since December 31, 2002, the Company has filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) with the SEC ("Company SEC Documents"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) The financial statements of the Company included in its annual report on Form 10-K for the fiscal year ended December 31, 2002 and in its quarterly report on Form 10-Q for the quarterly period ended June 30, 2003 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be

indicated in the notes thereto) and fairly present the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except as set forth in the Company SEC Documents, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the Company SEC Documents.

(c) The Common Stock is listed on the Nasdaq Stock Market and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Stock Market. The Company has not received any notification that, and has no knowledge that, the SEC or the National Association of Securities Dealers Inc. is contemplating terminating such listing or registration. The issuance of the shares of Purchased Stock pursuant to this Agreement does not require shareholder approval, including, without limitation, pursuant to the rules of the National Association of Securities Dealers Inc.

3.11 Absence of Changes. Since December 31, 2002, there has been no change or development which, individually or in the aggregate, has had or would have a Material Adverse Effect.

3.12 Disclosure Controls and Procedures. The Company has implemented the “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) required in order for the Chief Executive Officer and Chief Financial Officer of the Company to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects.

3.13 Intellectual Property. The Intellectual Property that is owned by the Company is owned free from any liens or restrictions, and all of the Company’s material Intellectual Property Licenses are in full force and effect in accordance with their terms, and are free of any liens or restrictions, except (a) where the failure to be free from such liens or restrictions would not have a Material Adverse Effect or (b) as set forth in any such Intellectual Property License. Except as set forth in the Company SEC Documents, there is no legal claim or demand of any Person pertaining to, or any proceeding which is pending or, to the knowledge of Company threatened, (i) challenging the right of the Company in respect of any Company Intellectual Property, or (ii) that claims that any default exists under any Intellectual Property License, except, in the case of (i) and (ii) above, where such legal claims would not have a Material Adverse Effect.

3.14 Offering. Subject to the accuracy of the Investor’s representations set forth in Section 4.3 and 4.4, the offer, sale and issuance of the Purchased Stock to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements.

3.15 No Integration. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Purchased Stock sold

pursuant to this Agreement in a manner that would require the registration of the Purchased Stock under the Securities Act.

3.16 Brokers' or Finders' Fees. No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement.

**ARTICLE 4**  
**REPRESENTATIONS AND WARRANTIES OF THE INVESTOR**

The Investor hereby represents and warrants as of the date hereof as follows:

4.1 Organization; Good Standing. The Investor is a corporation duly organized, validly existing and in good standing under the laws of Delaware. The Investor has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to purchase the Purchased Stock and to carry out the other transactions contemplated under the Transaction Agreements.

4.2 Authorization. All corporate action on the part of the Investor, and its directors and stockholders necessary for the authorization, execution and delivery of the Transaction Agreements, the performance of all obligations of the Investor thereunder, including the subscription and purchase of the Purchased Stock, has been taken. This Agreement has been duly executed and delivered by the Investor and, upon due execution and delivery by the Company, constitutes a valid and legally binding obligation of the Investor, enforceable against the Investor in accordance with its terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).

4.3 Purchase Entirely for Own Account. The Purchased Stock shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation, or otherwise distributing the Purchased Stock. The Investor does not have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Purchased Stock.

4.4 Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Purchased Stock to be purchased hereunder.

**ARTICLE 5**  
**FURTHER ASSURANCES; SECURITIES LAW MATTERS**

5.1 Further Assurances. The parties agree to take such reasonable steps and execute such other and further documents as may be necessary or appropriate to cause the terms and conditions contained herein to be carried into effect.

5.2 Restricted Securities. The Investor understands that the Purchased Stock, when issued, shall be “restricted securities” under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, the Investor represents that it is familiar with Rule 144 of the Securities Act, as presently in effect (“Rule 144”).

### 5.3 Limitations on Dispositions.

(a) For a period of two (2) years from the Closing Date, neither the Investor nor any of its Affiliates shall make any Disposition, except, upon prior written notice to the Company, to an Affiliate of the Investor, which Affiliate shall then be subject to the same restrictions on Disposition as set forth in this Section 5.3. The Investor or its Affiliate, as the case may be, (i) during the period from the day after the second anniversary of the Closing Date until the third anniversary of the Closing Date, may Dispose of no more than 250,000 shares (subject to stock splits, reverse stock splits, combinations, recapitalizations and similar events) of the Purchased Stock in the aggregate per calendar quarter, and (ii) after the third anniversary of the Closing Date, may Dispose of no more than 500,000 shares (subject to stock splits, reverse stock splits, combinations, recapitalizations and similar events) of the Purchased Stock in the aggregate per calendar quarter.

(b) With respect to any sale or transfer of the Purchased Stock, the Investor or its Affiliate, as the case may be, shall not make any such sale or transfer unless the sale or transfer is made pursuant to Rule 144 or similar provisions of federal securities laws as in effect from time to time.

(c) In the event the Company proposes to sell securities in an underwritten offering, the Investor shall, if requested by the Company and an underwriter of Common Stock of the Company, agree not to sell or otherwise transfer or dispose of any Common Stock of the Company held by the Investor for a specified period of time, such period of time not to exceed ninety (90) days. Such agreement shall be in writing in a form satisfactory to the Company and underwriter in such offering. The Company may impose stop transfer instructions with respect to the Common Stock subject to the foregoing restrictions until the end of the lock-up period. The Company may request no more than one (1) lock-up period per calendar year.

### 5.4 Legends. It is understood that the certificates representing the Purchased Stock shall bear the following legends:

(a) “These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to the Company) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act.”; and

(b) any legend required by applicable state securities laws.

5.5 Current Public Information. For so long as the Company remains a public company or, if earlier, until such time as the Investor no longer holds any shares of Purchased Stock, the Company shall:

(a) make and keep available, at all times, adequate public information as required under paragraph (c) of Rule 144 under the Securities Act; and

(b) file with the SEC in a timely manner all reports and other documents required of the Company under Sections 13, 14, and 15(d) of the Exchange Act.

5.6 Form D; Blue Sky Laws. The Company agrees to timely file a Form D with respect to the Purchased Stock as required under Regulation D after the Closing and to provide a copy thereof to the Investor promptly after such filing. The Company shall, on or before the Closing Date, take such action as the Company shall reasonably determine is necessary to qualify the Purchased Stock for sale pursuant to this Agreement under applicable securities or "blue sky" laws of the states of the United States or obtain exemption therefrom, and shall provide evidence of any such action so taken to the Purchaser on or prior to the Closing Date.

5.7 Listing. Prior to any sale of the Purchased Stock by the Investor, the Company will take all action necessary to enable the Purchased Stock to trade on the Nasdaq Stock Market.

## **ARTICLE 6 MISCELLANEOUS**

6.1 Remedies. In case any one or more of the representations, warranties, covenants or agreements set forth in this Agreement shall have been breached by any party hereto, the party or parties entitled to the benefit of such covenants or agreements may proceed to protect and enforce their rights either by suit in equity or action at law, including, but not limited to, an action for damages as a result of any such breach or an action for specific performance of any such covenant or agreement contained in this Agreement. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

6.2 Successors and Assigns. Except as otherwise expressly provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either party without (a) the prior written consent of the Company in the case of any assignment by the Investor, or (b) the prior written consent of the Investor in the case of any assignment by the Company, except in each case to any third party who acquires all or substantially all of the business of the assigning party by merger, sale of assets or otherwise. Notwithstanding the foregoing, upon prior written notice to the Company, the Investor may assign the right and obligation to purchase the Purchased Stock for the Purchase Price, and all of its other rights and obligations hereunder, to any of its Affiliates; provided that the Investor shall remain liable for the performance of the obligations such Affiliate.

6.3 Entire Agreement. This Agreement contains the complete understanding of the parties to this Agreement with respect to the subject matter hereof and supersedes all prior understandings and writings relating to the subject matter hereof.

6.4 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to conflict of laws principles. Each of the parties irrevocably and unconditionally consents to the exclusive jurisdiction of the courts of the State of New York, and the United States District Court for the Southern District of New York for any action, suit, or proceeding arising out of or relating to this Agreement, waives any objections to such jurisdiction and venue and agrees not to commence any action, suit or proceeding relating to this Agreement except in such courts.

6.5 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

6.6 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

6.7 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth below and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service, or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

To the Company:           Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill Road  
Tarrytown, NY 10591  
Attention: General Counsel

With a copy (which shall not constitute notice) to:           Skadden, Arps, Slate, Meagher & Flom LLP  
4 Times Square  
New York, NY 10036  
Attention: David J. Goldschmidt, Esq.

To the Investor: Aventis Inc.  
Somerset Corporate Center  
300 Somerset Corporate Boulevard  
Bridgewater, NJ 08807  
Attention: Owen Ball,  
Senior Corporate Counsel

and:

Aventis Pharmaceuticals Inc.  
200 Crossing Boulevard  
Bridgewater, New Jersey 08807  
Attention: Vice President,  
Legal Corporate Development

With a copy (which shall not constitute notice) to: Morgan, Lewis & Bockius, LLP  
502 Carnegie Center  
Princeton, New Jersey 08540  
Attention: Randall B. Sunberg, Esq.

6.8 Expenses. Each party shall pay its own fees and expenses with respect to this Agreement and the transactions contemplated hereby.

6.9 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Investor.

6.10 Severability. If, under applicable laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement ("Severed Clause"), then, it is mutually agreed that this Agreement shall endure except for the Severed Clause. The parties to this Agreement shall consult and use their reasonable best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement.

**[Signature Page Follows]**

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

AVENTIS PHARMACEUTICALS INC.

By: /s/ Gerald P. Belle

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Name: Gerald P. Belle  
Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski

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Name: Stuart Kolinski  
Title: General Counsel

**NON-EXCLUSIVE PATENT LICENSE AGREEMENT**

**between**

**MERCK & CO., INC.**

**and**

**REGENERON PHARMACEUTICALS, INC.**

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## NON-EXCLUSIVE PATENT LICENSE AGREEMENT

THIS AGREEMENT effective as of 18 August, 2003, (the "Effective Date") between Merck & Co., Inc., a New Jersey corporation ("Merck") and Regeneron Pharmaceuticals, Inc., a New York corporation ("Regeneron").

### Background:

Regeneron desires to obtain a non-exclusive license under the Patent Rights, upon the terms set out in this Agreement, and Merck desires to grant such a license.

Merck and Regeneron (each, a "Party", and collectively, the Parties) agree as follows:

### 1. DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

- 1.1 **"Affiliate"** means (i) any corporation or business entity of which fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a Party; or (ii) any corporation or business entity which, directly or indirectly, owns, controls or holds fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of a Party; or (iii) any corporation or business entity of which fifty percent (50%) (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (i) or (ii).
- 1.2 **"Common Stock"** is defined in Section 4.1.
- 1.3 **"Field"** means all uses of Products.
- 1.4 **"Information"** means any and all information and data, including without limitation all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by or on behalf of one Party to the other Party in connection with this Agreement.
- 1.5 **"Market Price"** means (a) if the Common Stock is listed on a national securities exchange, the average of the high and low of the price per share of such security quoted by The Nasdaq Stock Market, Inc. ("NASDAQ") or, if no such high and low prices are quoted by NASDAQ, the average of the closing bid and asked prices as officially

reported on the principal national securities exchange on which such security is then listed or admitted to trading; or (b) if the Common Stock is not then listed or admitted to trading on any national securities exchange but is designated as a national market system security by the National Association of Securities Dealers, Inc., the average of the high and low trading price of the Common Stock.

- 1.6** “**Net Sales**” means the gross invoice price of Product sold by Regeneron and its Sublicensees to the first third party (other than any Sublicensee) in an arm’s length transaction after deducting, if not previously deducted, from the amount invoiced or received:
- (a) trade, cash and quantity discounts;
  - (b) returns, credits, rebates, chargebacks and other allowances;
  - (c) retroactive price reductions that are actually allowed or granted;
  - (d) sales commissions paid to independent third party distributors and/or selling agents;
  - (e) sales taxes, excise taxes, tariffs, duties and other governmental charges;
  - (f) freight and other transportation costs itemized in the invoice to the third party customer; and
  - (g) bad debt.
- 1.7** “**Product**” means any preparation for sale by prescription, over-the-counter, or any other method, containing one or more compounds that [\*\*\*\*\*].
- 1.8** “**Patent Rights**” means those patents and patent applications listed on Schedule 1.8 and all Patents claiming priority thereto or arising therefrom. The term “Patent” includes patents and patent applications, whether domestic or foreign, including all provisionals, and all divisions, continuations, continuations-in-part, reissues, renewals, extensions, supplementary protection certificates of any such patents and patent applications.
- 1.9** “**Rule 144**” means Rule 144 under the Securities Act of 1933.
- 1.10** “**Sales Date**” means the date that Merck is first permitted to sell the shares under Rule 144 (or if such date is not a business day, the next succeeding business day).
- 1.11** “**Shares**” is defined in Section 4.1.
- 1.12** “**Territory**” means all of the countries in the world, and their territories and possessions.
- 1.13** “**Valid Patent Claim**” means a claim of an issued, or granted, and unexpired patent included within the Patent Rights, which has not been held revoked or unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction,

and which decision is not appealable or has not been appealed within the time allowed for appeal; and which has not been admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or other proceeding.

## **2. LICENSE**

### **2.1 Non-exclusive License Grant**

Merck hereby grants to Regeneron a non-exclusive license in the Territory to practice under the Patent Rights to make, have made, use, import, sell and offer to sell Products in the Field. This license shall be non-transferable and non-sublicensable, except that Regeneron is entitled to grant sublicenses to practice under the Patent Rights (i) to its Affiliates, and (ii) to third parties, but solely to the extent necessary to enable such Affiliates and third parties to make, have made, use, import, sell and offer to sell Products in the Field together with Regeneron or on Regeneron's behalf (entities in (i) and (ii) referred to as "Sublicensees"). Sublicensees include, as an example, third parties or Affiliates that license intellectual property rights to Products from Regeneron in addition to any sublicense under the Patents.

If the making, having made, use, offer for sale, sale or import by Regeneron or its Sublicensees of Axokine<sup>®</sup> or an Axokine derivative for treating obesity or obesity related disorder would infringe during the term of this Agreement a method or use claim which Merck (or any of its Affiliates) owns on the Effective Date and which claim is not covered by the grant in Section 2.1, Merck hereby grants to Regeneron to the extent Merck (or its Affiliate) is legally able to do so, a non-exclusive license in the Territory under such claim solely for Regeneron and its Sublicensees to develop, make, have made, use, sell, offer to sell or import Axokine or Axokine derivatives for such disorders, and in such case, such claim shall be treated as part of the Patent Rights licensed under this Agreement for all purposes, including royalty obligations. Merck agrees that neither it nor any of its Affiliates shall take any action that would restrict Merck's ability to grant Regeneron the non-exclusive license referred to in this Section 2.1. For the purpose of this Section, the term "Axokine" shall have the meaning set out in Schedule 2.1.

### **2.2 Sublicensees**

If a Sublicensee sells Product, such sales by those Sublicensees shall be treated as Net Sales, and are subject to royalties under Article 4. Regeneron shall remain responsible for the performance of its Sublicensees. In the event of a material default by any Sublicensee under a sublicense, Regeneron will promptly notify Merck and take such action to remedy such default. In addition, all sublicenses must comply with the following requirements:

- (a)** the sublicense is wholly consistent with the terms of this Agreement and in particular, such sublicense does not purport to extend or continue in any circumstances rights under the Patent Rights after this Agreement is effectively terminated;
- (b)** the sublicense is in the English language, executed by the Sublicensee and giving its place of business;

- (c) the sublicense precludes the Sublicensee granting further sublicenses and the sublicense to the Patent Rights terminates automatically upon the termination of this Agreement;
- (d) the sublicense obliges the Sublicensee to maintain insurance in respect to its activities pursuant to their respective sublicenses in a manner consistent with Regeneron's obligations under Section 7.5; and
- (e) the sublicense provides an indemnity from the Sublicensee in favor of Merck and Merck Indemnitees to the same extent as the indemnity contained in Section 7.3, and the sublicense specifically agrees that it will not challenge the standing of Merck if its seek to rely on such indemnification.

A breach of any sublicense agreement by a third party Sublicensee shall not be deemed a breach by Regeneron under this Agreement that could give rise to termination under Section 6.4.

### **3. CONFIDENTIALITY AND PUBLICATION**

#### **3.1 Nondisclosure Obligation**

All Information disclosed by or on behalf of one Party to the other Party under this Agreement shall be maintained in confidence by the receiving Party and shall not be disclosed to non-Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:

- (a) is known by receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
- (b) is properly in the public domain;
- (c) is subsequently disclosed to the receiving Party by a third party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;
- (d) is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records;

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

If a Party is required by judicial or administrative process to disclose Information that is subject to the non-disclosure provisions of this Section 3.1, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-

use provisions of this Section 3.1, and the Party disclosing Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.

### **3.2 Publicity/Use of Names**

No disclosure of the existence of, or the terms of, this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, such permission not to be unreasonably withheld or delayed, and except as may be required by law. Notwithstanding the foregoing, Regeneron shall be permitted to disclose in its filings with the Securities and Exchange Commission ("SEC") those terms of this Agreement which it reasonably determines are required to be disclosed by law and file a redacted version this Agreement with the SEC as an exhibit to such a filing. Merck shall have an opportunity to review and comment on such redacted version of this Agreement before it is filed with the SEC.

## **4. PAYMENTS; ROYALTIES AND REPORTS**

### **4.1 Consideration for License**

In consideration for the licenses granted in Section 2.1, upon the terms contained herein, Regeneron shall pay Merck the following compensation:

- (a) Within five business days of the Effective Date, Regeneron shall issue to Merck or its designee one hundred nine thousand four hundred fifty (109,450) authorized shares (the "Shares") of Regeneron Common Stock, par value \$0.001 per share (the "Common Stock"). The number of Shares determined by dividing one million five hundred thousand (1,500,000.00) by the Market Price of each Share of Common Stock on August 18, 2003, with the number of shares being rounded up the nearest whole number.
- (b) No later than ten business days after the Effective Date, Regeneron will deliver a certificate or certificates for the Shares issued to Merck (or its designee) pursuant to Section 4.1(a) of this Agreement. The Shares shall be registered in the name of Merck (or its designee).
- (c) [\*\*\*\*\*] upon approval from the relevant regulatory authority to market and sell a Product in the United States, France, Germany, Italy, Spain, or the United Kingdom (whichever approval is the first to occur). Regeneron shall promptly notify Merck of such approval, and deliver payment within thirty (30) days of such approval. This payment will be made only once, upon the first such approval, regardless of the number of times such regulatory approval is achieved.

## 4.2 Shares

The certificate representing the Shares shall bear a legend substantially in the following form:

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SHARES UNDER SUCH ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO THE COMPANY) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF SUCH ACT.

In the event that the aggregate Market Price of the Shares on the Sales Date is less than one million five hundred thousand dollars (\$1,500,000.00), and Regeneron did not previously exercise the Regeneron Buy Back Right, Merck shall notify Regeneron of the amount of such shortfall and within thirty (30) days of receipt of such notice, Regeneron shall make a cash payment to Merck (or its designee) for the difference between: (x) the aggregate Market Price of the Shares on the Sales Date; and (y) one million five hundred thousand dollars (\$1,500,000.00). Merck and its Affiliates shall not be permitted to engage in any short sale or other hedging transaction (or similar purchase of derivative securities with respect to the Common Stock) without Regeneron's prior consent, and any gain on such hedging transactions shall reduce the "shortfall" payment referred to above.

In the event that the aggregate Market Price of the Shares on the Sales Date is greater than one million six hundred and fifty thousand dollars (\$1,650,000.00) and Regeneron did not previously exercise the Regeneron Buy Back Right, within thirty (30) days of the Sales Date Merck shall, at its option and in its sole discretion, either: (a) make a cash payment to Regeneron in an amount equal to the difference between (x) one million six hundred and fifty thousand dollars (\$1,650,000.00) and (y) the aggregate Market Price of the Shares on the Sales Date (such amount the "Excess Amount"); or (b) return to Regeneron a number of Shares equal to the Excess Amount divided by the Market Price of one share of Common Stock on the Sales Date; provided, that if this formula results in a fractional amount of shares, Merck shall round up to the nearest whole number of shares.

Regeneron represents and warrants that the Shares issued to Merck shall be validly issued and fully paid and non-assessable, issued in compliance with all applicable federal and state securities laws and free from all liens. At Merck's request, on or after the Sales Date, Regeneron will use all reasonable efforts to cause its transfer agent to comply with Merck's (or its designee's) request to transfer the Shares in accordance with Rule 144. Regeneron shall have the right at any time prior to the Sales Date to provide notice to Merck requiring Merck to sell the Shares to Regeneron for a purchase price equal to the greater of (a) one million five hundred thousand dollars (\$1,500,000.00) and (b) the lesser of (x) the Market Price of the Shares on the date of such notice and (y) one million six hundred fifty thousand dollars (\$1,650,000.00) (the "Regeneron Buy Back Right"). The settlement of the Share repurchase shall occur not later than ten (10) business days after the delivery of the Regeneron Buy Back Right notice to Merck.

#### 4.3 Royalties

Regeneron shall pay Merck royalties for the sale of Product whose production, use, sale, offer to sell, or import, would, but for the license granted in Section 2.1, infringe (either by direct, contributory, or inducement) a Valid Patent Claim. Solely for the purposes of this Agreement, there is a rebuttable presumption that the sale of a Product in the Territory is for the treatment of obesity. Without limitation, Regeneron shall be able to rely on a nationally recognized pharmaceutical sales data service, such as IMS Health, to rebut this presumption. Royalties shall be in an amount equal to:

- (a) [\*\*\*\*\*] of that portion of total annual Net Sales of Products by Regeneron or its Sublicensees that is less than or equal to [\*\*\*\*\*];
- (b) [\*\*\*\*\*] of that portion of total annual Net Sales of Products by Regeneron or its Sublicensees that is greater than [\*\*\*\*\*];
- (c) [\*\*\*\*\*] of that portion of total annual Net Sales of Products by Regeneron or its Sublicensees that is greater than [\*\*\*\*\*]; and
- (d) [\*\*\*\*\*] of that portion of total annual Net Sales of Products by Regeneron or its Sublicensees that is greater than [\*\*\*\*\*].

Annual Net Sales shall be determined on a calendar year basis (i.e., January 1 through December 31). By way of example, [\*\*\*\*\*.]

Royalties on each Product at the rate set forth above shall be effective as of the date of first commercial sale of Product and shall continue on a country-by-country basis until the expiration of the last Valid Patent Claim.

#### 4.4 Payment Exchange Rate

All payments to be made by Regeneron to Merck under this Agreement shall be made in United States dollars by bank wire transfer in immediately available funds to such bank account in the United States designated in writing by Merck from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the quarterly amount of currency equivalent in United States dollars due Merck shall be made at the rate of exchange published in The Wall Street Journal (National Edition) on the last business day of the calendar quarter in which Net Sales are calculated.

#### 4.5 Reports, Payment of Royalty

During the term of the Agreement following the first commercial sale of Product, Regeneron shall furnish to Merck a quarterly written report for each calendar quarter showing all Product Net Sales in the Territory for which a royalty is payable under Section 4.3 during the reporting period and the royalties payable under this Agreement. Reports shall be due on the sixtieth (60) day following the close of each calendar quarter following the first commercial sale

of Product. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Regeneron shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. Merck and its agents shall treat all information provided to it under this Article IV as Regeneron's Information.

Any income or other tax that Regeneron or its Sublicensees is required to withhold and pay with respect to royalties or other amounts payable under this Agreement shall be deducted from and offset against said payments prior to remittance to Merck; provided, however, that in regard to any tax so deducted, Regeneron or its Sublicensee shall give or cause to be given to Merck such assistance as may reasonably be necessary to enable Merck to claim exemption therefrom or credit therefore, and in each case shall furnish Merck proper evidence of the taxes paid on its behalf.

#### **4.6 Audits**

- a) Upon the written request of Merck, Regeneron shall permit an independent certified public accounting firm of nationally recognized standing selected by Merck and reasonably acceptable to Regeneron, at Merck's expense, to have access (upon at least thirty (30) days prior written notice) during normal business hours to such of the records of Regeneron as may be reasonably necessary to verify the accuracy of the royalty reports for any year ending not more than thirty-six (36) months prior to the date of such request. No more than one such audit may occur during any twelve (12) month period. The accounting firm shall enter into a separate confidentiality agreement with Regeneron and shall disclose to Merck only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies.
- b) If such accounting firm correctly identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within thirty (30) days of the date Merck delivers to Regeneron such accounting firm's written report. The fees charged by such accounting firm shall be paid by Merck, provided, however, that if audit uncovers an underpayment of royalties by Regeneron that exceeds the greater of [\*\*\*\*\*].
- c) Regeneron shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to make reports to Regeneron, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Merck's independent accountant under the same conditions and to the same extent required of Regeneron under this Agreement.

#### **5. REPRESENTATIONS AND WARRANTIES; DISCLAIMER OF WARRANTIES**

- a) Regeneron represents that it has the requisite corporate power and authority to execute and deliver this Agreement, and issue the Shares, and perform the transactions contemplated by this Agreement. The execution, delivery and performance by Regeneron of this Agreement and the issuance by Regeneron of the Shares each have been duly authorized by all necessary corporate, stockholder and other required action, as

the case may be.

- b) Regeneron warrants that neither the execution, delivery or performance by Regeneron of this Agreement nor the consummation of the transactions contemplated hereby (A) will result in any breach of any provision of the charter or by-laws of the Regeneron; or (B) will result in any violation or breach of any law, regulation, order, judgment, writ, injunction, license, permit, agreement or instrument to which Regeneron (or any of its Affiliates) is subject.
- c) Merck represents that it has the requisite corporate power and authority to execute and deliver this Agreement, and grant the license described in Section 2.1. The execution, delivery and performance by Merck of this Agreement have been duly authorized by all necessary corporate action.
- d) Merck warrants that neither the execution, delivery or performance by Merck of this Agreement nor the consummation of the transactions contemplated hereby (A) will result in any breach of any provision of the charter or by-laws of Merck; or (B) will result in any violation or breach of any law, regulation, order, judgment, writ, injunction, license, permit, agreement or instrument to which Merck (or any of its Affiliates) is subject.
- e) Merck warrants to the best of its knowledge it is the owner of the Patent Rights licensed in this Agreement and that it has the authority to grant such license.
- f) **DISCLAIMER:** THE PATENTS RIGHTS ARE PROVIDED “AS IS” AND NEITHER PARTY NOR ITS AFFILIATES MAKE ANY WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER OTHER THAN THOSE EXPRESSLY SET OUT IN THIS AGREEMENT. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUCTED AS A WARRANTY OR REPRESENTATION CONCERNING THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY PRODUCT DEVELOPED BY REGENERON AS A RESULT OF REGENERON’S USE OF THE PATENT RIGHTS, OR THE COMMERCIAL VALUE OR VALIDITY OF THE PATENT RIGHTS. EXCEPT ARISING FROM A BREACH OF ITS REPRESENTATIONS OR WARRANTIES CONTAINED HEREIN, MERCK AND ITS AFFILIATES WILL NOT BE LIABLE TO REGNERON FOR ANY DIRECT, CONSEQUENTIAL OR OTHER DAMAGES OR LOST PROFITS OR LOST BUSINESS OPPORTUNITY ALLEGEDLY SUFFERED BY REGENERON OR ANY OTHER RESULTING FROM ANY PRODUCT DEVELOPED BY REGENERON. MERCK EXPRESSLY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE ACTIVITIES OF REGENERON PURSUANT TO THE LICENSE GRANTED HEREIN WILL NOT INFRINGE ANY PATENT OWNED BY A THIRD PARTY. THIS AGREEMENT SHALL NOT BE CONSTRUED AS AN ADMISSION OF ANY PARTY THAT ANY PATENT RIGHT IS OR IS NOT VALID, INFRINGED, OR ENFORCEABLE.

## **6. TERM AND TERMINATION**

### **6.1 Term and Expiration**

This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 6.2, 6.3 or 6.4, this Agreement shall continue in effect until expiration of the last Valid Patent Claims.

### **6.2 Termination by Regeneron**

Notwithstanding anything contained herein to the contrary, Regeneron shall have the right to terminate this Agreement at any time in its sole discretion by giving ninety (90) days' advance written notice to Merck. In the event of termination under this Section 6.2: (i) Regeneron shall pay all amounts then due and owing as of the termination date; and (ii) except for the surviving provisions set forth in Section 6.5, the rights and obligations of the Parties shall terminate as of the date of such termination.

### **6.3 Termination by Merck**

Notwithstanding anything contained herein to the contrary, if Regeneron or its Affiliates directly or indirectly challenges or assist any third party to challenge the validity of the Patent Rights, Merck is entitled to immediately terminate this Agreement under this Section 6.3; and (i) Regeneron shall pay all amounts then due and owing as of the termination date; and (ii) except for the surviving provisions set forth in Section 6.5, the rights and obligations of the Parties shall terminate as of the date of such termination. Regeneron shall include substantially similar restrictions in its sublicense agreements with Sublicensees.

Notwithstanding the foregoing, nothing herein shall prohibit Regeneron or any of its Sublicensees from either (i) asserting any and all defenses available to it, including without limitation, assertions relating to the validity or enforceability of any Patent Right, in any suit or proceeding brought against it or its suppliers, distributors, Sublicensees, vendors or customers alleging the infringement of any Patent Right, or (ii) asserting any and all defenses, evidence and arguments, including without limitation, lack of patent ability of the subject matter of a count or claim and lack of support for a count or claim in an interference involving a Patent Right where the U.S. Patent Office on its own suggested a claim for the purposes of provoking an interference, and the actions described in this sentence shall not give Merck the right to terminate this Agreement.

### **6.4 Termination for Cause**

This Agreement may be terminated at any time during the term of this Agreement:

- a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within ninety (90) days after notice requesting cure of the breach; provided, however, in the event of a good faith dispute with respect to the existence of a material

breach, the ninety (90) day cure period shall be tolled until such time as the dispute is resolved pursuant to Section 7.10;

- b) by Merck upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by Regeneron; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if Regeneron consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

All rights and licenses granted under or pursuant to this Agreement to Regeneron are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (or any similar foreign legislation), licenses to “intellectual property” as defined under Section 101 of the United States Bankruptcy Code (or any similar foreign legislation). The Parties agree that, to the extent permitted by law, Regeneron shall retain all licenses granted to it hereunder and may fully exercise all of its rights and elections under the applicable bankruptcy code, subject to the terms of this Agreement.

#### **6.5 Effect of Expiration or Termination; Survival**

Upon termination of this Agreement under Section 6.2, 6.3 or 6.4, Regeneron’s license pursuant to Section 2.1 shall terminate. Expiration or termination of the Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. No termination of this Agreement shall relieve Regeneron of liability for any payment (including royalties for Products) accruing prior to the effective date of such termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination. The provisions of Article 3 shall survive the expiration or termination of the Agreement and shall continue in effect for ten (10) years. In addition, the provisions of Articles 1, 4 (including, for the avoidance of doubt, the obligations of the Parties under Section 4.2) 5, 6, and 7 shall survive any expiration or termination of this Agreement.

### **7. MISCELLANEOUS**

#### **7.1 Force Majeure**

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in performing any obligation under the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

## 7.2 Assignment/ Change of Control

Merck is entitled to assign this Agreement, and shall provide Regeneron with written notice of any such assignment.. Regeneron is not entitled to assign or otherwise transfer this Agreement, or assign or transfer any right or obligation hereunder without the consent of Merck; provided, however, that Regeneron may, without such consent, assign the Agreement and its rights and obligations hereunder (i) to any Affiliate (provided that Regeneron shall remain responsible for the performance of such Affiliate), (ii) in connection with the transfer or sale of all or substantially all of its assets covered by or related to the license granted hereunder (which, as of the Effective Date, shall be deemed to include all of Regeneron's intellectual property related to AXOKINE), or (iii) in the event of a "Change of Control". Any attempted assignment not in accordance with this Section shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under the Agreement. For purposes of this Section, a "Change of Control" shall be deemed to occur if Regeneron is involved in a merger, reorganization or consolidation, or if there is a sale of all or substantially all of Regeneron assets or business relating to this Agreement or if a person or group other than the current controlling person or group shall effectively acquire control of the management and policies of such Party. This Agreement shall be binding upon the successors and permitted assigns of a Party.

## 7.3 Indemnification

Regeneron shall indemnify Merck and its Affiliates, and its and their employees, officers and directors ("Merck Indemnitees") against, and hold Merck and such Merck Indemnitees harmless from, any and all losses from third party claims to the extent arising from:

- (a) a breach by Regeneron of any of its warranties or obligations under this Agreement;
- (b) the testing, development, commercialization and manufacture of Products by Regeneron or its agents, collaborators or Sublicensees;
- (c) the storage, use, sale, shipping and marketing of Products by Regeneron and its agents and collaborators; and
- (d) any representations, express, implied or statutory made by Regeneron or its agents as to the efficacy or safety of Products, or use to be made by any purchaser or consumer of Products including, without limitation, representations made by reference to the labeling or packaging of the Product.

Notwithstanding the foregoing, no Merck Indemnitee shall be entitled to indemnification under this Section 7.3 against any losses arising out of (i) a Merck Indemnitee's negligence or willful misconduct, or (ii) a breach by Merck of any of its representations, warranties or obligations under this Agreement.

An Merck Indemnitee shall give prompt notice to Regeneron of any claim for which it may seek indemnification under this Section 7.3 and, provided that Regeneron is not contesting the

indemnity obligation, shall permit Regeneron to control any litigation relating to such claim and disposition of any claim; provided, however, that Regeneron shall not settle or otherwise resolve any claim that would materially adversely affect the Merck Indemnitee, without prior approval of the Merck Indemnitee. The Merck Indemnitees shall cooperate with Regeneron in defense of any claim for which indemnification is sought under this Agreement and shall not settle or offer to settle any such claim without Regeneron's prior written consent. If Regeneron elects to defend the claim, it shall not be responsible for attorneys' fees incurred by the Merck Indemnitees, provided that the Merck Indemnitees shall have the right to retain their own counsel, at their own expense. The failure by the Merck Indemnitee to deliver notice to Regeneron within a reasonable time after it becomes aware of any claim for which it seeks indemnification, if prejudicial to the ability to defend such claim, shall relieve Regeneron of any liability to the Merck Indemnitees under this Section 7.3.

#### **7.4 Liability**

Merck Not Liable. Merck and its Affiliates are not liable (in contract or tort or otherwise) to compensate Regeneron for any loss howsoever suffered by Regeneron arising directly or indirectly from the use of the Patent Rights, except for losses arising from (i) any breach of this Agreement by Merck (including a breach of any Merck representation or warranty), or (ii) Merck's (or its Affiliate's) negligence or willful misconduct.

#### **7.5 [\*\*\*\*\*]**

#### **7.6 Miscellaneous**

Nothing in this Agreement shall be construed as: (a) an obligation to bring or prosecute actions or suits against third parties infringement; of (b) conferring by implications, estoppel or otherwise, any license or rights under any patents or intellectual property of Merck or its Affiliates other than the Patent Rights. Merck shall have the exclusive right to take action against any infringement of any of the Patent Rights, in its sole discretion. Regeneron shall cooperate reasonably in any action Merck (or its Affiliates) take against any infringement by a third party upon Merck's request and at Merck's expense; provided that nothing shall require Regeneron to authorize the disclosure of Information if it reasonably determines that such disclosure will harm its business.

#### **7.7 Severability**

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

## 7.8 Notices

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Regeneron, to:                   Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, NY 10591-6707  
Attention: President  
Facsimile No.: [\*\*\*\*\*]

and:                                       Attention: Vice President and General Counsel  
Facsimile No.: [\*\*\*\*\*]

if to Merck, to:                       Merck & Co., Inc.  
One Merck Drive  
P.O. Box 100, WS3A-65  
Whitehouse Station, NJ 08889-0100  
Attention: Office of Secretary  
Facsimile No.: [\*\*\*\*\*]

And                                       Merck & Co., Inc.  
One Merck Drive  
Attention: Vice President and Chief Licensing Officer  
P.O. Box 100, WS2A-30  
Whitehouse Station, NJ 08889-0100  
Facsimile: [\*\*\*\*\*]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day; (b) on the business day after dispatch if sent by nationally-recognized overnight courier; and/or (c) on the fifth business day following the date of mailing if sent by mail.

## 7.9 Applicable Law

The Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey and the patent laws of the United States without reference to any rules of conflict of laws or renvoi. The United Nations Convention on the Sale of Goods shall not apply.

## 7.10 Dispute Resolution

**7.10.1**       The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If

the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an “Excluded Claim” shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (“AAA”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

- 7.10.2** The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within 30 days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within 30 days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English.
- 7.10.3** Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ and any administrative fees of arbitration.
- 7.10.4** Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.
- 7.10.5** The parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither party may terminate the Agreement until final resolution of the dispute through arbitration or other judicial determination. The parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.
- 7.10.6** As used in this Section, the term “**Excluded Claim**” shall mean a dispute, controversy or claim that concerns (a) the validity or infringement of a patent; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

#### **7.11 Entire Agreement; Amendments**

The Agreement contains the entire understanding of the Parties with respect to the licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the Patent Rights and the licenses granted hereunder are superseded by the terms of this Agreement. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

## **7.12 Headings**

The captions to the several Articles and Sections hereof are not a part of the Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

## **7.13 Independent Contractors**

It is expressly agreed that Regeneron and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Regeneron nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

## **7.14 Waiver**

The waiver by either Party hereto of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

## **7.15 Cumulative Remedies**

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

## **7.16 Waiver of Rule of Construction**

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

## **7.17 Counterparts**

The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

**MERCK & CO., INC.**

By: /s/ Richard N. Kender

Richard N. Kender  
Vice President Business Development  
& Corporate Licensing

August 18, 2003

Date

**REGENERON  
PHARMACEUTICALS, INC.**

By: /s/ Murray A. Goldberg

Name: Murray A. Goldberg  
Title: Senior Vice President,  
Finance & Administration

August 18, 2003

Date

**SCHEDULES**

**SCHEDULE 1.8 PATENT RIGHTS**

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**SCHEDULE 2.1**

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November 11, 2003

Board of Directors  
Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, New York 10591

Dear Directors:

We are providing this letter to you for inclusion as an exhibit to your Form 10-Q filing pursuant to Item 601 of Regulation S-K.

We have been provided a copy of the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2003. Footnote 2 therein describes a change in accounting principle from recognizing collaborative and other research and development revenue pursuant to the method described as the EITF 91-6 method to the substantive milestone method. It should be understood that the preferability of one acceptable method of accounting over another for revenue recognition for those types of revenues has not been addressed in any authoritative accounting literature, and in expressing our concurrence below we have relied on management's determination that this change in accounting principle is preferable. Based on our reading of management's stated reasons and justification for this change in accounting principle in the Form 10-Q, and our discussions with management as to their judgment about the relevant business planning factors relating to the change, we concur with management that such change represents, in the Company's circumstances, the adoption of a preferable accounting principle in conformity with Accounting Principles Board Opinion No. 20.

We have not audited any financial statements of the Company as of any date or for any period subsequent to December 31, 2002. Accordingly, our comments are subject to change upon completion of an audit of the financial statements covering the period of the accounting change.

Very truly yours,

PricewaterhouseCoopers LLP

**Certification of CEO and CFO Pursuant to  
Rule 13a-14(a) under the Securities Exchange Act  
of 1934, as Adopted Pursuant to  
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Leonard S. Schleifer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
  2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
    - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's
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auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2003

By: /s/ Leonard S. Schleifer

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Leonard S. Schleifer, M.D., Ph.D.  
President and Chief Executive Officer

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I, Murray A. Goldberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
  2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this quarterly report is being prepared;
    - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
    - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
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b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2003

By: /s/ Murray A. Goldberg

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Murray A. Goldberg  
Senior Vice President, Finance & Administration, Chief  
Financial Officer, Treasurer, and Assistant Secretary

**Certification of CEO and CFO Pursuant to  
18 U.S.C. Section 1350,  
As Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ending September 30, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Leonard S. Schleifer

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Leonard S. Schleifer, M.D., Ph.D.  
Chief Executive Officer  
November 12, 2003

/s/ Murray A. Goldberg

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Murray A. Goldberg  
Chief Financial Officer  
November 12, 2003

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of § 18 of the Securities Exchange Act of 1934, as amended.